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U.S. Food and Drug Administration
Center for Devices and Radiological Health
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10903 New Hampshire Ave
Silver Spring, MD 20993-0002

**Attn**: Dr. Anthony Lee (Robotic Assisted Surgery Devices Team, Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices, Office of Product Evaluation and Quality | Center for Devices and Radiological Health, FDA

**Re**: K214095, *da Vinci X/Xi* (IS4200/IS4000) 8mm Reusable Instruments; Response to Additional Information Request dated February 25, 2022

Dear Dr. Lee,

In response to the Additional Information Request regarding K214095, *da Vinci X/Xi* (IS4200/IS4000) 8mm Reusable Instruments, dated February 25, 2022, Intuitive Surgical is submitting the enclosed responses to the four questions in the request.

If you have any questions or need additional information, please contact me using the information provided below. Thank you for your review of this submission.

Best Regards,

Kunal Gunjal

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## FDA Question 1(Reprocessing, Sterility and Shelf-Life)

*You provided Justification, Cleaning Efficacy for 18 Clinical Uses, da Vinci X/Xi 8mm Instruments in Appendix B of your submission to justify relying on existing cleaning validation testing conducted with the predicate device (K170645) and not conducting new cleaning validation to support the extended uses of the da Vinci X/Xi 8 mm instruments. With your justification, you conducted testing on two device types used in reliability testing to demonstrate that two design features, distal seal and flush tube, maintain flow rate specifications over the extended simulated surgical use and reprocessing cycles. Although these features may mitigate ingress of soil and facilitate removal of soil, testing of these features is not adequate to demonstrate that the instruments can still be effectively cleaned following additional uses and reprocessing cycles.*

- *The da Vinci Xi instruments are delicate surgical instruments with complex internal structures that cannot be visually inspected for soil and present a significant challenge to reprocessing.*

- *Increased usage and reprocessing itself may introduce damage to internal surfaces and cables that is not evident and may retain soil. The retention of soil by damaged surfaces and cables presents an increased challenge to the cleaning procedures.*

- *Although you previously showed no significant soil accumulation after 9 uses of the test instruments, you have not evaluated the instruments for incremental build-up of soil beyond 9 uses and up to the specified limited number of uses for each instrument.*

*An inadequately cleaned device may prevent successful subsequent sterilization and allow for cross-contamination leading to patient infection. Therefore, please provide the protocol and results of new cleaning validation testing (manual and automated) on each subject instrument (or justified worst case representative devices) after simulated surgical use and repeated reprocessing at the end of its proposed use life. In addition, please address the following regarding your test devices:*

*a) Please evaluate the instruments for soil accumulation to the new specified use life, prior to final cleaning.*

*b) Please provide a robust side-by-side comparison to justify use of specified worst case representative instruments for testing, if used.*

*c) Please prepare/condition test instruments to end of use life using simulated surgical use (or actual clinical use) procedures and repeated manual and/or automated cleaning processes, as directed in the proposed labeling.*

*This information is needed to ensure that you have adequately addressed reprocessing and sterility considerations which may impact the safety and/or effectiveness of your device.*



 

**ISI Response**

As requested by FDA, we have performed cleaning validation for the *da Vinci X/Xi* 8mm Extended Life Instruments (subject devices) to validate the efficacy of two cleaning methods:

- Manual cleaning process
- Automated cleaning process using a compatible cleared washer/disinfector manufactured by STERIS Corporation (*Trade Name/Device Name: RAS 12 Rack, RAS 12 Long Rack, RAS Cycle of the AMSCO 7052HP/ 7053HP Single Chamber Washer/Disinfector)*

The cleaning validation was performed in accordance with the following standards and guidance documents:

- FDA Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*, document issued on: March 17, 2015 (Amended on June 9, 2017).
- AAMI TIR 12:2020 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR 30: 2011/(R)2016, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- ANSI/AAMI ST15883-1:2009/(R) 2014, Washer-disinfectors: General requirements, terms and definitions and tests

Cleaning Validation testing consisted of two elements: Recovery Efficiency and Cleaning Efficacy. The Recovery Efficiency was performed to determine the efficiency of the extraction process in recovering test soil from the devices. The Cleaning Efficacy test evaluated the efficacy of the manual cleaning process and the automated cleaning process (*as described in the Reprocessing Instructions*) for the devices using qualitative visual inspection and two quantitative endpoints, protein and hemoglobin.

The Cleaning Efficacy was performed on a Master Product selected from the *da Vinci X/Xi* 8mm Extended Life Instruments Family (subject devices). The Cleaning Validation utilized 13 test samples of the Master Product, one positive control, and one negative control. The recovery efficiency evaluation utilized 3 test samples of the Master Product and one negative control.

**Table 1-1** summarizes the test samples in the Cleaning Validation.

**Table 1-1: Cleaning Validation Sample Size**

| Type of Validation | Devices |
|---|---|
| Recovery Efficiency | 3 test samples and 1 negative control |
| Cleaning Efficacy | 13 test samples, 1 positive control, and 1 negative control |

### Master Product for Cleaning Validation for *da Vinci X/Xi* 8mm Extended Lives Instruments

Master Products were selected as the devices that represent the greatest challenge for the cleaning process. The Master Products were selected based on the following criteria:

- Instrument that collects the largest volume of soil in the inner shaft
- Instrument that has the potential to have the highest amount of soil on the tip
- Instrument that has the hardest to reach areas to remove soil
- Instrument from which soil is most difficult to remove
- Instruments with the smallest spaces between components
- Instruments with interfaces between different materials
- Instruments with the lowest flushing efficacy

**Table 1-2** summarizes the Master Product selected for the purpose of Cleaning Validations for the *da Vinci X/Xi* 8mm Extended Lives Instruments.

**Table 1-2: Master Products for Cleaning Validations**

| Product Family | Master Product for Cleaning Validation | Master Product Justification |
|---|---|---|
| *da Vinci* IS4000/IS4200 8mm Extended Lives Instruments | IS4000/IS4200 8mm Maryland Bipolar Forceps (MBF), P/N: 471172 | **P/N: 1097982 (Appendix A1)** |

### Recovery Efficiency

Recovery efficiency was performed to determine the efficiency of the extraction process in recovering test soil from the *da Vinci X/Xi* 8mm Instruments. The test consisted of the following steps: soiling, drying, and recovering by exhaustive extraction.

For the instrument shaft, a known amount of soil was injected, allowed to dry, and recovered by exhaustive extraction. For the instrument tip, the tip was dipped in soil, allowed to dry, and recovered by exhaustive extraction. Exhaustive extraction was performed until the protein and hemoglobin levels in the extracts are below the limit of detection.

The recovery efficiency for each instrument (Instrument Tips and Instrument Shafts were independently calculated for both protein and hemoglobin), as follows:

$$Recovery\ Efficiency = \frac{Protein/Hg\ recovered\ in\ the\ 1^{st}\ extract}{Sum\ of\ protein/Hg\ recovered\ in\ all\ extracts} X\ 100\%$$

Recovery Efficiency Testing was conducted on the Master product, *da Vinci X/Xi* 8mm Maryland Bipolar Forceps, PN 470172 as a part of the manual cleaning validation study which was included in the predicate device 510(k) submission (K203632) as listed in **Table 1-3.**

**Table 1-3: Recovery Efficiency Test Protocol and Test Report**

| Master Product | Recovery Efficiency Test Protocol | Recovery Efficiency Test Report |
|---|---|---|
| IS4000 Maryland Bipolar Forceps (MBF)<br>(P/N: 470172) | 862106-18P, Attachment 6 (provided as Appendix C1 in the predicate device submission, K203632).<br><br>For ease of review this protocol is provided in this submission as **Appendix A2.** | 862106-18R (provided as Appendix C2 in the predicate device submission, K203632).<br><br>For ease of review this report is provided in this submission as **Appendix A3.** |

**Rationale for Applicability of the Recovery Efficiency Values established in the Manual Cleaning validation study of the predicate device (MBF PN 470172) to the Manual Cleaning Validation study of the subject device (MBF PN 471172)**

The *da Vinci X/Xi* 8mm Maryland Bipolar Forceps, PN 470172 (master product used for the manual cleaning validation of predicate devices) and *da Vinci X/Xi* 8mm Maryland Bipolar Forceps, PN 471172 (master product used for the manual cleaning validation of subject devices) are identical in design. The different part numbers (PN) are used to designate the number of use lives for each part. Additionally, the manual cleaning process validated for both the subject and predicate devices are identical.

The tip soiling and extraction methods are identical between the predicate device manual cleaning validation study (PN 862106-18R provided in this submission as **Appendix A3**) and the subject device manual cleaning validation study (PN 1097984-01R provided in this submission as **Appendix A5**). Hence, the tip recovery efficiency values established in manual cleaning

validation study for the predicate device are applicable to subject device manual cleaning validation study.

There is one difference in the test method to note between the predicate and subject device manual cleaning validations. The shaft soiling performed in the predicate device manual cleaning validation study (PN 862106-18R provided in this submission as **Appendix A3**) used [redacted] of coagulating sheep's blood, whereas the subject device manual cleaning validation study (PN 1097984-01R provided in this submission as **Appendix A5**) used [redacted] of coagulating sheep's blood (which was determined using a soiling characterization study described in PN 1040204-01R which is provided as **Appendix A10** in this submission). This study determined the amount of soil present after one surgical use for the predicate devices (*da Vinci X/Xi* 8mm instruments) suite in a simulated clinical environment. Since there are no design differences between the subject and predicate devices and the subject devices are used in the same clinical environment as the predicate devices, the soiling characterization study performed on the predicate device applies to the subject devices. Recovery efficiency is performed by soiling the shaft with coagulating sheep's blood, letting the soil dry for [redacted] and then performing extractions until the protein and hemoglobin levels in the extracts are below the limit of detection. The recovery efficiency is calculated by dividing the protein or hemoglobin value from the first extraction by the sum of protein and hemoglobin from all extractions. These recovery efficiency values are then used at the end of the study after the test instruments, negative control, and positive control are extracted. The protein and hemoglobin values from the test, negative, and positive control instruments are divided by the recovery efficiency in order to represent the worst-case where not all soil was recovered in the extraction. A higher shaft soil load will require more extractions before protein and hemoglobin reach the limit of detection and therefore will result in a lower recovery efficiency. Using this recovery efficiency for a smaller soil load will create a worst-case for the final protein and hemoglobin values. Additionally, the shaft extraction method used within the predicate and subject device manual cleaning validation study is identical. Therefore, the shaft recovery efficiency values from the predicate device manual cleaning validation study (PN 862106-18R provided in this submission as **Appendix A3**) are applicable to the subject device manual cleaning validation study (PN 1097984-01R provided in this submission as **Appendix A5**), as a worst-case.

Hence, extraction recovery efficiency was not repeated as part of the manual cleaning validation study for the *da Vinci X/Xi* 8mm Extended Lives Instruments (subject devices).

**Rationale for Applicability of the Recovery Efficiency Values established in the Manual Cleaning validation study of the predicate device (MBF PN 470172) to the Automated Cleaning Validation study of the subject device (MBF PN 471172)**

As stated above, there are no design differences between the *da Vinci X/Xi* 8mm Maryland Bipolar Forceps, PN 470172 (master product used for the manual cleaning validation of

predicate devices) and *da Vinci X/Xi* 8mm Maryland Bipolar Forceps, PN 471172 (master product used for the automated cleaning validation of subject devices).

Differences exist between manual and automated cleaning validations by necessity, as shown in in test report PN 862106-18R (provided in this submission as **Appendix A3** which validates a manual cleaning process for the predicate devices) and PN 1097996-01R (provided in this submission as **Appendix A7** which validates an automated cleaning process for the *da Vinci X/Xi* 8mm Extended Lives Instruments i.e., subject devices). However, the differences in the cleaning processes do not impact the validity of the recovery efficiency results obtained during the manual cleaning validation study and its applicability to the automated cleaning validation study for the following reasons:

- The tip soiling and extraction methods are identical between the manual cleaning validation study for the predicate device (PN 862106-18R provided in this submission as **Appendix A3**) and the automated cleaning validation study for the subject devices (PN 1097996-01R provided in this submission as **Appendix A7**). Hence, the tip recovery efficiency values established in manual cleaning validation study for the predicate devices are applicable to the automated cleaning validation study for the subject devices.
- The shaft soiling performed in the manual cleaning validation study for the predicate device (PN 862106-18R provided in this submission as **Appendix A3**) used [redacted] of coagulating sheep's blood, and the automated cleaning validation study for the subject devices (PN 1097996-01R provided in this submission as **Appendix A7**) used [redacted] of coagulating sheep's blood (which was determined using a soiling characterization study described in PN 1040204-01R which is provided as **Appendix A10** in this submission). This study determined the amount of soil present after one surgical use for the predicate devices (*da Vinci X/Xi* 8mm instruments) suite in a simulated clinical environment. Since there are no design differences between the subject and predicate devices and the subject devices are used in the same clinical environment as the predicate devices, the soiling characterization study performed on the predicate device applies to the subject devices. Recovery efficiency is performed by soiling the shaft with coagulating sheep's blood, letting the soil dry for [redacted] and then performing extractions until the protein and hemoglobin levels in the extracts are below the limit of detection. The recovery efficiency is calculated by dividing the protein or hemoglobin value from the first extraction by the sum of protein and hemoglobin from all extractions. These recovery efficiency values are then used at the end of the study after the test instruments, negative control, and positive control are extracted. The protein and hemoglobin values from the test, negative, and positive control instruments are divided by the recovery efficiency in order to represent the worst-case where not all soil was recovered in the extraction. A higher shaft soil load will require more extractions before protein and hemoglobin reach the limit of detection and therefore will result in a lower recovery efficiency. Using this recovery efficiency for a smaller soil load will create a worst-case for the final protein

and hemoglobin values. Additionally, the shaft extraction method in the manual cleaning validation study for the predicate devices is identical to the automated cleaning validation study for the subject devices. Therefore, the shaft recovery efficiency values from the manual cleaning validation study for the predicate devices (PN 862106-18R provided in this submission as **Appendix A3**) are applicable to the automated cleaning validation study for the subject devices (PN 1097996-01R provided in this submission as **Appendix A7**), as a worst-case.

Hence, extraction recovery efficiency was not repeated as part of the automated cleaning validation study for the *da Vinci X/Xi* 8mm Extended Lives Instruments (subject devices) using the Steris Washer-Disinfector.

The Recovery Efficiency results are summarized in **Table 1-4**

**Table 1-4: Recovery Efficiency Results – Protein and Hemoglobin**

| Master Product | Protein | | Hemoglobin | |
|---|---|---|---|---|
| | Tip | Shaft | Tip | Shaft |
| IS4000/IS4200 Maryland Bipolar Forceps (P/N: 470172) | [redacted] | [redacted] | [redacted] | [redacted] |

**Cleaning Efficacy**

The Cleaning Efficacy test evaluated the efficacy of the manual cleaning process and the automated cleaning process using a Steris Washer-Disinfector (*as described in the Reprocessing Instructions*) for the *da Vinci X/Xi* 8mm Extended Life Instruments using qualitative visual inspection and two quantitative endpoints, protein and hemoglobin.

This testing method is intended to demonstrate the acceptable cleanliness characteristics of devices through the end of their clinical life cycle. For each of the Master Products, cleaning efficacy testing was performed using a sample size of 15 devices. The 15 devices consisted of 1 negative control, 1 positive control, and 13 test samples. Cleaning Efficacy Test Protocols and Test Reports are included in this submission and are listed in **Table 1-5**.

**Table 1-5: Cleaning Efficacy Test Protocol and Test Report**

| Master Products | Cleaning Method | Cleaning Efficacy Test Protocol | Cleaning Efficacy Test Report |
|---|---|---|---|
| IS4000/IS4200 Maryland Bipolar Forceps (MBF) (P/N: 471172) | Manual Cleaning Process | PN 1097984-01P (provided in this submission as **Appendix A4**) | PN 1097984-01R (provided in this submission as **Appendix A5**) |
| | Automated Cleaning Process using Steris Washer-Disinfector | PN 1097996-01P (provided in this submission as **Appendix A6**) | PN 1097996-01R (provided in this submission as **Appendix A7**) |

All 15 devices underwent a single cycle of baseline reprocessing, just as an instrument would prior to initial clinical use.

**Number of Cycles:** Following baseline reprocessing, the test devices and negative device control were subjected to a cumulative of 17 soiling and reprocessing cycles, representative of what an instrument will undergo prior to the final clinical use as instruments are not reprocessed after the final (18th) clinical use. The maximum number of clinical uses within the suite of Extended Life Instruments is 18 clinical uses. Although the number of clinical uses for the Master Product, Maryland Bipolar Forceps (PN 471172) is 14, MBF tested to 18 clinical lives represents the worst-case scenario for cleaning efficacy for the suite of *da Vinci X/Xi* 8mm Extended Life Instruments (*refer to PN 1097982, Master Product Justification for Cleaning Efficacy Validations of da Vinci X/Xi 8mm Extended Use Instruments provided as* ***Appendix A1*** *in this submission*).

**Test Devices:** Following baseline reprocessing, thirteen (13) test devices were subjected to a cumulative of 17 soiling and reprocessing cycles representative of what an instrument will undergo prior to the final clinical use. The maximum number of clinical uses within the suite of Extended Life Instruments (subject devices) is 18 clinical uses.

For the final soiling-reprocessing cycle (Cycle 17), the Thermal Disinfection, Lubrication, and Package and Sterilize steps were not performed. Due to the thermal effects on proteins, it is not possible to assess residual protein and hemoglobin on instruments that have been subjected to disinfection or autoclave sterilization temperatures. Furthermore, the presence of steam permeable lubricant can interfere with the optical measurements used for residual protein and hemoglobin quantification. Hence, to maintain the validity of the analytical residual protein and hemoglobin testing, the lubrication step and the sterilization step was omitted from reprocessing for the final soiling-reprocessing cycle (Cycle 17) for the test devices.

**Negative Device Control:** One (1) negative device control underwent 17 reprocessing cycles. Negative device control was not soiled. For the final reprocessing cycle (Cycle 17), the Thermal Disinfection, Lubrication, and Package and Sterilize steps was not performed. Due to the thermal effects on proteins, it is not possible to assess residual protein and hemoglobin on instruments that have been subjected to disinfection or autoclave sterilization temperatures. Furthermore, the presence of steam permeable lubricant can interfere with the optical measurements used for residual protein and hemoglobin quantification. Hence, to maintain the validity of the analytical residual protein and hemoglobin testing, the lubrication step and the sterilization step was omitted from reprocessing for the final reprocessing cycle (Cycle 17) for the negative device control.

The test devices and negative device control were visually inspected at 4x magnification after each cycle. This was done in line with the reprocessing instructions which instructs users to perform an inspection of the instrument under 4x magnification after the cleaning process is completed.

After the final cycle, all devices were visually inspected at 4x magnification, extracted, disassembled, and internal and external disassembled components were visually inspected at 10x magnification (*Note: Inspection of the Instrument's internal and external disassembled components under 10x magnification is done per the test protocol*). The extracts were analyzed for residual protein and hemoglobin.

**Positive Device Control:** One (1) positive device control was subjected to a single soiling cycle. The positive device control was not cleaned. The positive device control was subjected to visual inspection at 10x magnification, which was followed by extraction. The extract was analyzed for residual protein and hemoglobin.

**Simulated Surgical Use (SSU):** The *da Vinci X/Xi* 8mm Extended Life Instruments will be used in both sterile and non-sterile body cavities. Per AAMI TIR30, whole blood or a dilution of blood or serum is appropriate for this type of device application. The devices were soiled under simulated surgical use conditions with the application of whole heparinized sheep's blood and energy for tissue cautery. After completion of each SSU, the device was secondarily soiled. The inner shaft of the devices was soiled with coagulating sheep's blood, as this location is the most difficult to clean. In addition, the devices were subjected to a tip dip in coagulating sheep's blood.

- **Primary Soiling with Simulated Use:** Devices were subjected to multiple dips into sheep's blood, followed by end effector manipulations and the application of energy for tissue cautery to mimic worst-case clinical soiling. The sequence and quantity of discrete end effectors maneuvers and the applications of cautery energy were based on anticipated clinical use for each device type. Simulated use soiling instructions for the MBF instruments are documented in PN 865041-03 which is provided in **Appendix A8** in this submission. Simulated Use was performed with a system installed with Instrument Product Quality Assurance (iPQA) software. iPQA software is an Internal

ISI Software build intended to perform the final motion check on instruments without decrementing a use from the total uses remaining. Maryland Bipolar Forceps (PN 471172) are indicated for 14 clinical lives but were tested to 17 SSUs to represent the worst-case scenario for cleaning efficacy. Thus, to cycle the MBFs past their intended life, iPQA software was required on a test system. iPQA software is functionally identical to commercially released software with the exception that it does not decrement uses from instruments. SSUs performed using the iPQA software build is equivalent to testing using formal software builds.

- **Secondary Shaft Soiling:** Device tips and shafts were soiled after simulated use. The amount of soil to be applied to the inner shafts was [redacted] and was determined using a soiling characterization study described in PN 1040204-01R which is provided as **Appendix A10** in this submission. The Soiling Characterization Protocol (PN 1040204-01P) is provided in this submission as **Appendix A9**. This study determined the amount of soil present after one surgical use for the predicate devices (*da Vinci X/Xi* 8mm instruments) suite in a simulated clinical environment. Since there are no design differences between the subject and predicate devices and the subject devices are used in the same clinical environment as the predicate devices, the soiling characterization study performed on the predicate device applies to the subject devices.

**Reprocessing:** The study tested the worst-case reprocessing instructions. The point-of-use procedures were omitted, allowing soils to completely dry prior to initiating the cleaning procedure.

- ***Automated Reprocessing***: The thermal disinfection step and sterilization step was omitted from the final reprocessing cycle (Cycle 17). Due to the thermal effects on proteins and soils, it is not possible to assess for residual protein and hemoglobin on instruments that have been subjected to disinfection or autoclave sterilization temperatures. Hence, to maintain the validity of the analytical residual protein and hemoglobin testing, the disinfection and sterilization step were omitted from the reprocessing procedure for the final reprocessing cycle (Cycle 17). Additionally, to avoid potential interference for analysis caused by residual lubricant, lubrication was not performed in the final cycle (Cycle 17).
- ***Manual Reprocessing***: The disinfection step was omitted from all reprocessing cycles because disinfection is defined as an optional step in the Manual Reprocessing Instructions. The sterilization step was omitted from the final reprocessing cycle (Cycle 17). Due to the thermal effects on proteins and soils, it is not possible to assess for residual protein and hemoglobin on instruments that have been subjected to disinfection or autoclave sterilization temperatures. Hence, to maintain the validity of the analytical residual protein and hemoglobin testing, the sterilization step was omitted from the reprocessing procedure for the final reprocessing cycle (Cycle 17). Additionally, to avoid potential interference for analysis caused by residual lubricant, lubrication was not performed in the final cycle (Cycle 17).

The durations of the rinse, spray, and brush steps were [redacted] for the test protocol cleaning process steps. The temperature and minimum concentration recommended by the detergent manufacturer was used.

The cleaning instructions along with the steps/values that were used in the cleaning studies are outlined in **Table 1-6 and Table 1-7.**

**Table 1-6: Reprocessing Steps and Parameters (Manual Cleaning validation)**

| Step | Description | Reprocessing Steps from Reprocessing Instructions | Values for Cleaning Validation (*Refer to Attachment 3, PN 1097984-01P, provided as Appendix A4 in this submission*) |
|---|---|---|---|
| Point of Use | | | |
| 1 | Preparation in the Operating Room | Cold water or with pH-neutral enzymatic cleaner. Unspecified time to transport | Omitted |
| Point of Processing/Decontamination | | | |
| 2 | Prepare Detergent and Immerse | Fully submerge the instruments in pH-neutral enzymatic detergent at manufacturer's recommended concentration and temperature (not to exceed 1% concentration for alkaline detergent). | Fully submerge the instruments in pH-neutral enzymatic detergent at manufacturer's recommended concentration and temperature. Detergent type, concentration and temperature to be recorded in data sheets. |
| 3 | Prime | Prime | Inject 15mL of the detergent using a syringe into flush port #1. |
| 4 | Prime | Soak the instruments for 30 minutes. | Soak the instruments for [redacted] |
| 5 | Flush | Flush each flush port for a minimum 20 seconds for each flush port with cold water at minimum 30 PSI | Flush each flush port for [redacted] for each flush port with cold water at [redacted] at [redacted] |



 

| Step | Description | Reprocessing Steps from Reprocessing Instructions | Values for Cleaning Validation (*Refer to Attachment 3, PN 1097984-01P, provided as Appendix A4 in this submission*) |
|---|---|---|---|
| 6 | Spray Tip | Spray the instrument tip using pressurized (at 30 PSI) cold water for 30 Seconds while moving the instrument tip several times through its full range of motion to ensure all surfaces are reached.<br><br>(NOTE: Perform while submerged in water) | Spray the instrument tip using pressurized (at [redacted]) cold water ([redacted]) for [redacted] while moving the instrument tip several times through its full range of motion to ensure all surfaces are reached.<br><br>(NOTE: Perform while submerged in water) |
| 7 | Brush | Thoroughly brush the tip, under running cold water, with a clean nylon brush for at least 60 seconds. While scrubbing, move the instrument wrist through its full range of motion | Thoroughly brush the tip, under running cold water, with a clean nylon brush for [redacted] While scrubbing, move the instrument wrist through its full range of motion. Document the amount of time each device was brushed. |
| 8 | Rinse | Minimum 60 seconds with running cold water | [redacted] with running cold water at [redacted] |
| 9 | Prime and Ultrasonic Clean | Fill the bath with pH-neutral to mildly alkaline enzymatic detergent at manufactures minimum recommended concentration and temperature (alkaline cleaners not to exceed 1% concentration). Prime the primary flush port with 15 mL of detergent. Ultrasonically clean for 15 minutes. | Fill the bath with pH-neutral enzymatic detergent at manufacturer's recommended concentration and temperature. Prime the primary flush port with [redacted] of detergent. Ultrasonically clean for [redacted] Detergent type and concentration to be recorded in report. |
| 10 | Flush Post-Ultrasonic Cleaning | Flush each flush port for a minimum 20 seconds for each flush port with cold water at minimum 30 PSI | Flush each flush port for [redacted] for each flush port with cold water at [redacted] at [redacted] . |
| 11 | Rinse | Minimum 60 seconds with running cold water or until all visible soil and cleaning agents are removed | [redacted] with running cold water at [redacted] |
| 12 | Thermal Disinfection | May be performed (optional) | Omitted |



 

| Step | Description | Reprocessing Steps from Reprocessing Instructions | Values for Cleaning Validation (*Refer to Attachment 3, PN 1097984-01P, provided as Appendix A4 in this submission*) |
|---|---|---|---|
| 13 | Dry and Inspect | Dry with lint-free cloth and compressed dry air<br><br>Inspect devices for soil with 4X magnification. If soil is found, repeat entire cleaning process. | Dry with lint-free cloth and compressed dry air<br><br>Inspect devices with 4X magnification.<br><br>After the final cleaning cycle and extraction, the devices will be disassembled and visually inspected at 10x magnification for visible soil. |
| 14 | Lubricate | Apply one to two drops of steam permeable, pH-neutral lubricant to instrument tip | Apply one to two drops of steam permeable, pH-neutral lubricant to instrument tip (omitted for cycle preceding extractions) |
| 15 | Package and Sterilization | 132 ˚C for 4 min (USA) | [redacted] for [redacted] (omitted for cycle preceding extractions) |
| 16 | Dry | 50 min. minimum | [redacted] minimum (omitted for cycle preceding extractions) |

**Table 1-7: Reprocessing Steps and Parameters (Automated Cleaning Validation)**

| Step | Description | Reprocessing Steps from Reprocessing Instructions | Values for Automated Cleaning Efficacy Validation (*Refer to Attachment 3, PN 1097996-01P, provided as Appendix A6 in this submission*) |
|---|---|---|---|
| Point of Use | | | |
| 1 | Preparation in the Operating Room | Cold water or with pH-neutral enzymatic cleaner. Unspecified time to transport | Omitted (Not Performed) |
| Point of Processing/Decontamination | | | |



 

| Step | Description | Reprocessing Steps from Reprocessing Instructions | Values for Automated Cleaning Efficacy Validation (*Refer to Attachment 3, PN 1097996-01P, provided as Appendix A6 in this submission*) |
|---|---|---|---|
| 2 | Prepare Detergent and Immerse | Fully submerge the instruments in pH-neutral to mildly alkaline enzymatic detergent at manufacturer's recommended concentration and temperature (not to exceed 1% concentration for alkaline detergent). | Fully submerge the instruments in pH-neutral detergent at manufacturer's recommended concentration and temperature. Detergent type, concentration and temperature to be recorded in data sheets. |
| 3 | Prime | Inject 15mL of the detergent using a syringe into flush port #1. | Inject [redacted] of the detergent using a syringe into flush port #1. |
| 4 | Soak | Soak the instruments for 10 minutes. | Soak the instruments for [redacted] |
| 5 | Spray Tip | Spray the instrument tip using pressurized (at 30 PSI) cold water for 30 Seconds while moving the instrument tip several times through its full range of motion to ensure all surfaces are reached.<br><br>(NOTE: Perform while submerged in water) | Spray the instrument tip using pressurized (at [redacted] cold water ([redacted]) for 27 Seconds. (NOTE: Perform while submerged in water) |
| 6 | Brush Tip | Thoroughly brush the tip, under running cold water, with a clean nylon brush for at least 60 seconds or until visually clean. While scrubbing, move the instrument wrist through its full range of motion. | Thoroughly brush the tip, under running cold water, with a clean nylon brush for [redacted] or until visually clean. While scrubbing, move the instrument wrist through its full range of motion. Document the amount of time each device was brushed. |
| 7 | Automated Cleaning | Load the instruments into the washer disinfector according to the manufacturer's instructions. Run the washing cycle dedicated to da Vinci instruments, including the specified detergent and concentration. | Load the instruments into the washer disinfector according to the manufacturer's instructions. Run the validation washing cycle dedicated to da Vinci instruments, including the specified detergent and concentration. |

| Step | Description | Reprocessing Steps from Reprocessing Instructions | Values for Automated Cleaning Efficacy Validation (*Refer to Attachment 3, PN 1097996-01P, provided as Appendix A6 in this submission*) |
|---|---|---|---|
| 8 | Thermal Disinfection | Performed as part of the automated cleaning cycle | Performed as part of the automated cleaning cycle (omitted for cycle preceding extractions) |
| 9 | Dry and Inspect | Dry with lint-free cloth and compressed dry air<br>Inspect devices for soil with 4X magnification. If soil is found, repeat the cleaning process. | Dry with lint-free cloth and compressed dry air<br>Inspect devices with 4X magnification.<br>After the final cleaning cycle and extraction, the devices will be disassembled and visually inspected at 10x magnification for visible soil. |
| 10 | Lubricate | Apply one to two drops of steam permeable, pH-neutral lubricant to instrument tip | Apply one to two drops of steam permeable, pH-neutral lubricant to instrument tip (omitted for cycle preceding extractions) |
| 11 | Package and Sterilization | 132 ˚C for 4 min (USA) | [redacted] for [redacted] (omitted for cycle preceding extractions) |
| 12 | Dry | 50 min. minimum | [redacted] minimum (omitted for cycle preceding extractions) |

**Extraction:** After the final soiling-cleaning cycle, the test devices and 1 negative device control were subjected to soil extraction and analysis. After one cycle of soiling, the one (1) positive device control was subjected to soil extraction and analysis. The instrument tips and inner shafts were extracted using 1% SDS which removes the residual protein and hemoglobin from the device. The extracts were analyzed for protein using the modified o-Phthalaldehyde protein assay (OPA) per WI 1005073 (provided as **Appendix A11** in this submission) and for hemoglobin using the Hemoglobin assay per WI 1021861 (provided as **Appendix A11** in this submission). Device extraction instructions are provided in Test Protocols listed in **Table 1-5**.

**Surface Area:** The extraction surface area of the instruments, which is necessary to determine if the residual protein and hemoglobin is within acceptable limits, is calculated from computer-generated solid models. The surface area was measured by considering only the extracted surfaces of the master product, Maryland Bipolar Forceps (PN 471172) for a surface area of 428.052 cm2.

**Visual Inspection:**

- ***For Test Devices and Negative Device Control***, after every soiling-cleaning cycle, the devices were visually inspected using 4x magnification. After the final soiling-cleaning cycle the devices were visually inspected using 4x magnification and then extracted. After extraction, the devices were disassembled and visually inspected at 10x magnification for visible soil.
- ***For the positive control device***, after one soiling cycle, the device was visually inspected using 10x magnification and then extracted.

**Figure 1-8** provides an Overview of the Manual and Automated Cleaning Validation study.

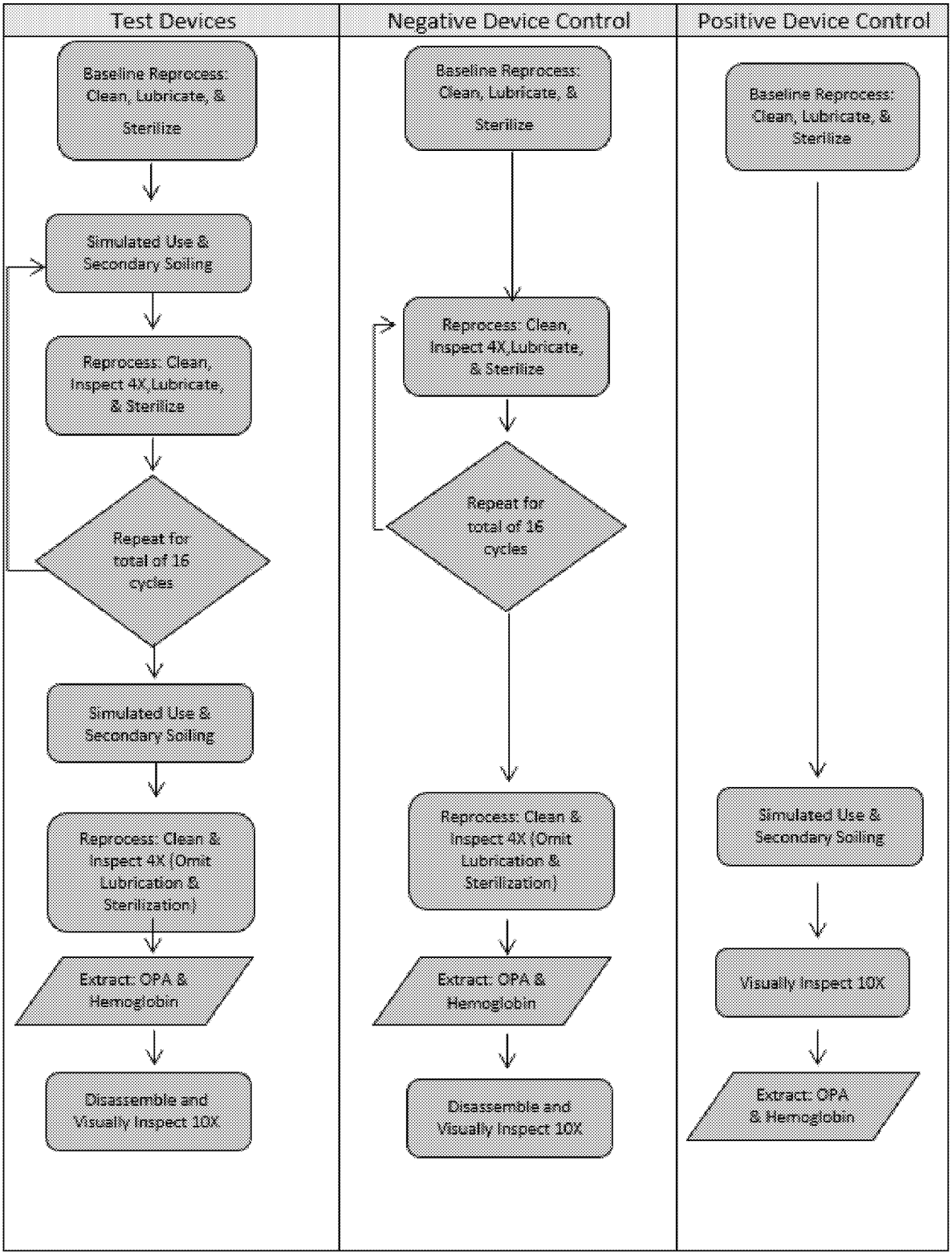


**Figure 1-8: Overview of the Manual and Automated Cleaning Validation study**

**Acceptance Criteria for Manual/Automated Cleaning Validation (IS4000/IS4200 8mm Extended Life Instruments)**

Using Visual Inspection as a marker:

- All the test devices and the negative device control must have no test soil observed during visual inspection using 4x magnification after every cleaning cycle.
- All the test devices and the negative device control must have no test soil observed during visual inspection using 10x magnification after extraction and disassembly.
- The positive device controls must have visible test soil using 10X magnification.

Using Protein as a marker:

**Table 1-9** provides the Acceptance Criteria for total residual protein for the negative device controls, positive device control, and test devices.

**Table 1-9: Acceptance Criteria for Total Residual Protein for the Negative Device Controls, Positive Device Controls, and Test Devices**

| Master Product | Positive Device Control | Test Devices and Negative Device Controls |
|---|---|---|
| IS4000/IS4200 Maryland Bipolar Forceps (MBF)<br>(P/N: 471172) | The positive device control must have a total residual protein corrected for recovery efficiency and adjusted for surface area [redacted] | All of the test devices and the negative device control shall have a total residual protein corrected for recovery efficiency and adjusted for surface area [redacted] |

Using Hemoglobin as a marker:

**Table 1-10** provides the Acceptance Criteria for total residual hemoglobin for the negative device controls, positive device control, and test devices.

**Table 1-10: Acceptance Criteria for Total Residual Hemoglobin for the Negative Device Controls, Positive Device Controls, and Test Devices**

| Master Product | Positive Device Control | Test Devices and Negative Device Controls |
|---|---|---|
| IS4000/IS4200 Maryland Bipolar Forceps (MBF)<br>(P/N: 471172) | The positive device control must have a total residual hemoglobin corrected for recovery efficiency and adjusted for surface area [redacted] | All of the test devices and the negative device control shall have a total residual hemoglobin corrected for recovery efficiency and adjusted for surface area [redacted] |



 

The rationale for the acceptance criteria for protein and hemoglobin values in the positive controls of IS4000/IS4200 8mm Extended Lives Instrument cleaning validations using sheep's blood as the test soil is provided as *PN 1097984-01R, Attachment 6 (provided as **Appendix A5** in this submission).*

## TEST RESULTS (MANUAL CLEANING VALIDATION)

The test sample information and test results for the manual cleaning validation are included in **Tables 1-11 through 1-14.**

**Table 1-11: Results of Visual Inspection of MBF (Manual Cleaning Validation)**

| Instrument | PN-Ver | Lot # - SN | 4X Visual Inspection Pass/Fail | 10X Visual Inspection Pass/Fail |
|---|---|---|---|---|
| Test Device 1 | 471172-17 | K10220124 0278 | Pass | Pass |
| Test Device 2 | 471172-17 | K10220124 0384 | Pass | Pass |
| Test Device 3 | 471172-17 | K10220124 0202 | Pass | Pass |
| Test Device 4 | 471172-17 | K10220124 0262 | Pass | Pass |
| Test Device 5 | 471172-17 | K10220124 0092 | Pass* | Pass |
| Test Device 6 | 471172-17 | K10220124 0373 | Pass | Pass |
| Test Device 7 | 471172-17 | K10220124 0056 | Pass | Pass |
| Test Device 8 | 471172-17 | K10220124 0265 | Pass | Pass |
| Test Device 9 | 471172-17 | K10220124 0393 | Pass | Pass |
| Test Device 10 | 471172-17 | K10220124 0098 | Pass | Pass |
| Test Device 11 | 471172-17 | K10220124 0355 | Pass | Pass |
| Test Device 12 | 471172-17 | K10220124 0304 | Pass* | Pass |
| Test Device 13 | 471172-17 | K10220124 0153 | Pass* | Pass |
| Positive Device Control | 471172-17 | K10220124 0329 | N/A | Pass |
| Negative Device Control | 471172-17 | K10220124 0271 | Pass | Pass |

** NOTE: Soil was observed during 4X visual inspection of Test Device #13 during Reprocessing Cycle 3 and Test Device #5 and #12 during Reprocessing Cycle 5. Refer to Discrepancy (Item # 3) in the Test Report PN 1097984-01R (provided as **Appendix A5**) which includes the justification/resolution for this discrepancy.*

**Table 1-12: Total Residual Protein for MBF (Corrected for Turbidity)- Manual Cleaning Validation**

| Instrument | Total Protein (µg /cm²) | Pass/Fail<br>Test samples and negative controls pass if [redacted]<br>Positive controls pass if [redacted] |
|---|---|---|
| Test Device 1 | [redacted] | Pass |
| Test Device 2 | | Pass |
| Test Device 3 | | Pass |
| Test Device 4 | | Pass |
| Test Device 5 | | Pass |
| Test Device 6 | | Pass |
| Test Device 7 | | Pass |
| Test Device 8 | | Pass |
| Test Device 9 | | Pass |
| Test Device 10 | | Pass |
| Test Device 11 | | Pass |
| Test Device 12 | | Pass |
| Test Device 13 | | Pass |
| Positive Device Control | | Pass |
| Negative Device Control | | Pass |

**The LOD for the OPA method is [redacted] and extract volume was [redacted] so LOD for this study was [redacted] Normalized to surface area [redacted], the LOD was [redacted]*

**Table 1-13: Total Residual Protein for MBF (Not Corrected for Turbidity)- Manual Cleaning Validation**

| Instrument | Total Protein (µg /cm$^2$) | Pass/Fail Test samples and negative controls pass if [redacted] Positive controls pass if [redacted] |
|---|---|---|
| Test Device 1 | [redacted] | Pass |
| Test Device 2 | | Pass |
| Test Device 3 | | Pass |
| Test Device 4 | | Pass |
| Test Device 5 | | Pass |
| Test Device 6 | | Pass |
| Test Device 7 | | Pass |
| Test Device 8 | | Pass |
| Test Device 9 | | Pass |
| Test Device 10 | | Pass |
| Test Device 11 | | Pass |
| Test Device 12 | | Pass |
| Test Device 13 | | Pass |
| Positive Device Control | | Pass |
| Negative Device Control | | Pass |

**Table 1-14: Total Residual Hemoglobin for MBF- Manual Cleaning Validation**

| Instrument | Total Hemoglobin (µg /cm²) | Pass/Fail<br>Test samples and negative controls pass if [redacted]<br>Positive controls pass if [redacted] |
|---|---|---|
| Test Device 1 | [redacted] | Pass |
| Test Device 2 | | Pass |
| Test Device 3 | | Pass |
| Test Device 4 | | Pass |
| Test Device 5 | | Pass |
| Test Device 6 | | Pass |
| Test Device 7 | | Pass |
| Test Device 8 | | Pass |
| Test Device 9 | | Pass |
| Test Device 10 | | Pass |
| Test Device 11 | | Pass |
| Test Device 12 | | Pass |
| Test Device 13 | | Pass |
| Positive Device Control | | Pass |
| Negative Device Control | | Pass |

** The LOD for the hemoglobin method is [redacted] and extract volume was [redacted]), so LOD for this study was [redacted] Normalized to surface area [redacted], the LOD was [redacted].*

## TEST RESULTS (AUTOMATED CLEANING VALIDATION)

The test sample information and test results for the automated cleaning validation are included in **Tables 1-15 through 1-18.**

**Table 1-15: Results of Visual Inspection of MBF (Automated Cleaning Validation)**

| Instrument | PN-Ver | Lot # - SN | 4X Visual Inspection Pass/Fail | 10X Visual Inspection Pass/Fail |
|---|---|---|---|---|
| Test Device 1 | 471172-17 | K10220124 0336 | Pass | Pass |
| Test Device 2 | 471172-17 | K10220124 0347 | Pass | Pass |
| Test Device 3 | 471172-17 | K10220124 0191 | Pass | Pass |
| Test Device 4 | 471172-17 | K10220124 0394 | Pass | Pass |
| Test Device 5 | 471172-17 | K10220124 0247 | Pass | Pass |
| Test Device 6 | 471172-17 | K10220124 0046 | Pass | Pass |
| Test Device 7 | 471172-17 | K10220124 0258 | Pass | Pass |
| Test Device 8 | 471172-17 | K10220124 0361 | Pass | Pass |
| Test Device 9 | 471172-17 | K10220124 0360 | Pass | Pass |
| Test Device 10 | 471172-17 | K10220124 0372 | Pass | Pass |
| Test Device 11 | 471172-17 | K10220124 0391 | N/A* | N/A |
| Test Device 12 | 471172-17 | K10220124 0266 | Pass | Pass |
| Test Device 13 | 471172-17 | K10220124 0422 | Pass | Pass |
| Positive Device Control | 471172-17 | K10220124 0273 | Pass | Pass |
| Negative Device Control | 471172-17 | K10220124 0445 | Pass | Pass |

** One cautery wire on test device # 11 broke free of the distal grip during cycle 7 SSU. Refer to Discrepancy (Item # 2) in the Test Report PN 1097996-01R (provided as **Appendix A7**) which includes the justification/resolution for this discrepancy.*

**Table 1-16: Total Residual Protein for MBF (Corrected for Turbidity- Automated Cleaning Validation)**

| Instrument | Total Protein (µg /cm²) | Pass/Fail<br>Test samples and negative controls pass if [redacted]<br>Positive controls pass if [redacted] |
|---|---|---|
| Test Device 1 | [redacted] | Pass |
| Test Device 2 | | Pass |
| Test Device 3 | | Pass |
| Test Device 4 | | Pass |
| Test Device 5 | | Pass |
| Test Device 6 | | Pass |
| Test Device 7 | | Pass |
| Test Device 8 | | Pass |
| Test Device 9 | | Pass |
| Test Device 10 | | Pass |
| Test Device 11 | | N/A |
| Test Device 12 | | Pass |
| Test Device 13 | | Pass |
| Positive Device Control | | Pass |
| Negative Device Control | | Pass |

** One cautery wire on test device # 11 broke free of the distal grip during cycle 7 SSU. Refer to Discrepancy (Item # 2) in the Test Report PN 1097996-01R (provided as **Appendix A7**) which includes the justification/resolution for this discrepancy.*

*** The LOD for the OPA method is [redacted] and extract volume was [redacted] thus LOD for this study was [redacted] Normalized to surface area [redacted], the LOD was [redacted]*

**Table 1-17: Total Residual Protein for MBF (Not Corrected for Turbidity-Automated Cleaning Validation)**

| Instrument | Total Protein (µg /cm²) | Pass/Fail<br>Test samples and negative controls pass if [redacted]<br>Positive controls pass if [redacted] |
|---|---|---|
| Test Device 1 | [redacted] | Pass |
| Test Device 2 | | Pass |
| Test Device 3 | | Pass |
| Test Device 4 | | Pass |
| Test Device 5 | | Pass |
| Test Device 6 | | Pass |
| Test Device 7 | | Pass |
| Test Device 8 | | Pass |
| Test Device 9 | | Pass |
| Test Device 10 | | Pass |
| Test Device 11 | | N/A |
| Test Device 12 | | Pass |
| Test Device 13 | | Pass |
| Positive Device Control | | Pass |
| Negative Device Control | | Pass |

**One cautery wire on test device # 11 broke free of the distal grip during cycle 7 SSU. Refer to Discrepancy (Item # 2) in the Test Report PN 1097996-01R (provided as **Appendix A7**) which includes the justification/resolution for this discrepancy.*

**Table 1-18: Total Residual Hemoglobin for MBF (Automated Cleaning Validation)**

| Instrument | Total Hemoglobin (µg /cm²) | Pass/Fail<br>Test samples and negative controls pass if [redacted]<br>Positive controls pass if [redacted] |
|---|---|---|
| Test Device 1 | [redacted] | Pass |
| Test Device 2 | | Pass |
| Test Device 3 | | Pass |
| Test Device 4 | | Pass |
| Test Device 5 | | Pass |
| Test Device 6 | | Pass |
| Test Device 7 | | Pass |
| Test Device 8 | | Pass |
| Test Device 9 | | Pass |
| Test Device 10 | | Pass |
| Test Device 11 | | N/A |
| Test Device 12 | | Pass |
| Test Device 13 | | Pass |
| Positive Device Control | | Pass |
| Negative Device Control | | Pass |

*Note: The LOD for the hemoglobin method is [redacted] and extract volume was [redacted] thus the LOD for this study was [redacted] Normalized to surface area [redacted] the LOD was [redacted]*

**One cautery wire on test device # 11 broke free of the distal grip during cycle 7 SSU. Refer to Discrepancy (Item # 2) in the Test Report PN 1097996-01R (provided as **Appendix A7**) which includes the justification/resolution for this discrepancy.*

## CONCLUSION

The *da Vinci X/Xi* 8mm Extended Lives Instruments (subject devices) successfully met the acceptance criteria for all markers. The test results demonstrate that the subject devices can be cleaned using the following cleaning methods:

- Manual cleaning process
- Automated cleaning process using a compatible washer/disinfector manufactured by STERIS Corporation (*Trade Name/Device Name: RAS 12 Rack, RAS 12 Long Rack, RAS Cycle of the AMSCO 7052HP/ 7053HP Single Chamber Washer/Disinfector)*

## FDA Question 2 (EMC, Wireless, and Electrical, Mechanical and Thermal Safety)

*You state that no additional EMC or electrical safety testing was required, as the only change in this submission is the number of use lives. Please note that electrical safety and EMC standards requires evaluation to the full number of use lives to ensure there is no loss of basic safety or essential performance. By increasing the number of use and reprocessing cycles, the overall structural integrity of the device may be impacted after extended use. Accordingly, new testing should be performed with representative instruments stressed to the maximum use life. Please provide the full set of EMC and electrical safety data to FDA-recognized consensus standards. For additional information, refer to FDA guidance document, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" (https://www.fda.gov/media/87995/download). This information is needed to ensure that the extended life instruments do not impact the EMC and electrical safety profiles of the subject device.*

**ISI Response**

**Electrical Safety Testing**

Our selected test facility, Underwriters Laboratories (UL), had originally set a cycle limit of 20 sterilization cycles for the *da Vinci X/Xi* 8mm instruments (predicate devices rated for 10 lives), which was in accordance with the *IEC 60601-1:1988 + A1:1991 + A2:1995 under Clause 44.7* which requires that *"Compliance is checked by sterilizing or disinfecting the Equipment or Equipment part 20 times in accordance with the methods specified"*. We have met this standard for the predicate devices that were cleared under the submissions as listed in **Table 2-1**.

As FDA is aware, *IEC 60601-1 Ed. 3.1 b:2012*, under clause 11.6.6 requires that, *"The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the **EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**."* Based on this 3rd edition of the Electrical safety standard, the number of sterilization cycles that the instrument is exposed to during the Electrical safety testing should be equal to the instrument's number of lives and NOT the number of Reprocessing cycles which are listed in the Reprocessing Instructions (*Note: Maximum number of lives for the extended lives instruments/subject devices is 18 and Maximum number of Reprocessing cycles for the extended lives instruments/subject devices is 23 as listed in **Table 2-2***). Usually, the number of Reprocessing cycles for the *da Vinci X/Xi* 8mm instruments which are listed in the Reprocessing Instructions are NUMBER OF LIVES +5 i.e., 5 additional reprocessing cycles are usually added to the labeling as a safety margin, since there is a possibility that the Instruments may get reprocessed twice prior to use in a surgical procedure.

There are no design changes between the subject and predicate devices. Since, the subject device/instrument use life is under 20 lives (*subject device/instruments are rated for a maximum of 18 lives as listed in **Table 2-2***), we have not repeated this suite of testing, since the testing for the predicate devices (instruments rated for 10 lives) was done on instruments exposed to 20 sterilization cycles. Instead, we have included results from prior testing on the predicate device (which are summarized in **Tables 2-4 and 2-5**) and this testing applies to the *da Vinci X/Xi* 8mm Extended Lives Instruments (subject devices) as listed in **Table 2-2**.

**Table 2-1: Predicate Number of lives (uses) and reprocessing cycles for the *da Vinci X/Xi* 8mm Reusable Instruments**

| *da Vinci X/Xi 8mm Reusable Instruments* | Previous Configuration (Predicate Device) | | | 510(k) submissions in which IEC 60601-1 testing was performed on the predicate instruments after subjecting them to 20 sterilization cycles |
|---|---|---|---|---|
| | Model Number | Number of Lives | Number of Reprocessing Cycles | |
| 8mm Maryland Bipolar Forceps | 470172 | 10 | 15 | K131861 |
| 8mm Fenestrated Bipolar Forceps | 470205 | 10 | 15 | |
| 8mm Force Bipolar | 470405 | 10 | 15 | Cleared via Traditional 510(k), K180351. Electrical Safety Testing included in K131861 applies to this device. |
| 8mm Large Needle Driver | 470006 | 10 | 15 | K131861 |
| 8mm Mega SutureCut Needle Driver | 470309 | 10 | 15 | |
| 8mm Cadiere Forceps | 470049 | 10 | 15 | Cleared via Special 510(k), K150284. Electrical Safety Testing included in K131861 applies to this device. |
| 8mm ProGrasp Forceps | 470093 | 10 | 15 | K131861 |
| 8mm Micro Bipolar Forceps | 470171 | 10 | 15 | |
| 8mm Curved Bipolar Dissector | 470344 | 10 | 15 | |
| 8mm Long Bipolar Grasper | 470400 | 10 | 15 | Cleared via Special 510(k), K150837. Electrical Safety Testing included in K131861 applies to this device. |
| 8mm Large SutureCut Needle Driver | 470296 | 10 | 15 | Cleared via Special 510(k), K150284. Electrical Safety Testing included in K131861 applies to this device. |
| 8mm Long Tip Forceps | 470048 | 10 | 15 | K131861 |

| *da Vinci X/Xi 8mm Reusable Instruments* | Previous Configuration (Predicate Device) | | | 510(k) submissions in which IEC 60601-1 testing was performed on the predicate instruments after subjecting them to 20 sterilization cycles |
|---|---|---|---|---|
| | Model Number | Number of Lives | Number of Reprocessing Cycles | |
| 8mm Cobra Graspers | 470190 | 10 | 15 | Cleared via Special 510(k), K150284. Electrical Safety Testing included in K131861 applies to this device. |

Electrical Safety testing complies with the following standards and is summarized in Test Report provided by Underwriters Laboratories (UL), refer to UL Report PN 841011-02 which is provided as **Appendix B1** in this submission.

- *IEC 60601-2-2:2017, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (FR Recognition Number: 6-389)*
- *ANSI AAMI ES60601-1:2005/(R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (FR Recognition Number:19-46)*

Testing was performed on representative devices from the predicate IS4000/IS4200 Instrument family i.e., instruments rated for 10 clinical uses as listed in **Table 2-3**.

**Table 2-2: Predicate and Subject Number of lives (uses) and reprocessing cycles for the *da Vinci X/Xi* 8mm Reusable Instruments**

| *da Vinci X/Xi 8mm Reusable Instruments* | Previous Configuration (Predicate Device) | | | Extended Life Configuration (Subject Device) | | |
|---|---|---|---|---|---|---|
| | Model Number | Number of Lives | Number of Reprocessing Cycles | Model Number | Number of Lives | Number of Reprocessing Cycles |
| 8mm Maryland Bipolar Forceps | 470172 | 10 | 15 | 471172 | 14 | 19 |
| 8mm Fenestrated Bipolar Forceps | 470205 | 10 | 15 | 471205 | 14 | 19 |
| 8mm Force Bipolar | 470405 | 10 | 15 | 471405 | 12 | 17 |
| 8mm Large Needle Driver | 470006 | 10 | 15 | 471006 | 15 | 20 |
| 8mm Mega SutureCut Needle Driver | 470309 | 10 | 15 | 471309 | 15 | 20 |
| 8mm Cadiere Forceps | 470049 | 10 | 15 | 471049 | 18 | 23 |
| 8mm ProGrasp Forceps | 470093 | 10 | 15 | 471093 | 18 | 23 |
| 8mm Micro Bipolar Forceps | 470171 | 10 | 15 | 471171 | 14 | 19 |
| 8mm Curved Bipolar Dissector | 470344 | 10 | 15 | 471344 | 14 | 19 |
| 8mm Long Bipolar Grasper | 470400 | 10 | 15 | 471400 | 14 | 19 |
| 8mm Large SutureCut Needle Driver | 470296 | 10 | 15 | 471296 | 15 | 20 |
| 8mm Long Tip Forceps | 470048 | 10 | 15 | 471048 | 18 | 23 |
| 8mm Cobra Graspers | 470190 | 10 | 15 | 471190 | 18 | 23 |

The representative instruments that were chosen for the electrical safety testing within the predicate devices are listed in **Table 2-3**.

**Table 2-3: Representative instruments used for Electrical Safety Testing**

| *da Vinci X/Xi 8mm Reusable Instruments* | Previous Configuration (Predicate Device) | | |
|---|---|---|---|
| | Model Number | Number of Lives | Number of Reprocessing Cycles |
| 8mm Fenestrated Bipolar Forceps | 470205 | 10 | 15 |
| 8mm Large Needle Driver | 470006 | 10 | 15 |

**Rationale for instruments chosen from each family for Electrical Safety testing**

- *Non-energy Family:* Instruments in the Non-energy family are identical in materials and construction with the exception of the following:
  - Distal tip geometry, and in some cases, materials differ from instrument to instrument
  - Labeling on the Cover: Each instrument Cover is marked with its own instrument type
  - Single Finger Instruments have four Hypotube/tungsten Cable assemblies running from the proximal end to the distal end whereas Dual Jaw instruments have six Hypotube/tungsten Cable assemblies. Since these instruments are so similar it is fairly arbitrary which one we choose to evaluate. The Large Needle Driver was chosen for the testing for the following reasons:
    - Dual Jaw non-energy instruments have more parts contained in the Main Shaft than Single Finger instruments (Six Hypotube assemblies as opposed to four).
    - Needle Drivers are the most used non-energy instrument.

- *Bipolar Energy Family:* Instruments in the Bipolar Energy family are identical in materials and construction with the exception of the following:
  - Distal Tip geometry: The very distal tip of the instrument that applies energy to the tissue is made of the same material but differ in shape.
  - Labeling on the Cover: Each instrument Cover is marked with its own instrument type

The instruments in the Bipolar Energy instrument family are validated to be used on the same generator at the same settings. Since these instruments are so similar it is fairly arbitrary which one, we choose to evaluate. The Fenestrated Bipolar Instrument was chosen as the test article from the Bipolar Energy family.

**Electrical Safety Test Summary**

Testing was performed on the representative instruments (as listed in **Table 2-3**) after exposing them to 20 steam sterilization cycles (*Equipment sterilized by Prevacuum Cycle* [redacted] *for* [redacted] *Dry time of* [redacted] *for total of 20 cycles*). Summary of the test results are provided in **Table 2-4 and Table 2-5**. IS4000/IS4200 Extended life instruments (subject devices) as listed in **Table 2-2** have a maximum of 18 clinical uses and there are no design differences between the subject and predicate devices.

As FDA is aware, *IEC 60601-1 Ed. 3.1 b:2012*, under clause 11.6.6 requires that, *"The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the* ***EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE****."* Based on this 3rd edition of the Electrical safety standard, the number of sterilization cycles that the instrument is exposed to during the Electrical safety testing should be equal to the instrument's number of lives and NOT the number of Reprocessing cycles (*Note: Maximum number of lives for the extended lives instruments/subject devices is 18 and Maximum number of Reprocessing cycles for the extended lives instruments/subject devices is 23 as listed in* ***Table 2-2***). Usually, the number of Reprocessing cycles for the *da Vinci X/Xi* 8mm instruments which are listed in the Reprocessing Instructions are NUMBER OF LIVES +5 i.e., 5 additional reprocessing cycles are usually added to the labeling as a safety margin, since there is a possibility that the Instruments get reprocessed twice prior to use in a surgical procedure.

Hence, testing performed on the selected representative instruments from the predicate devices that were subjected to 20 steam sterilization cycles, applies to the subject devices (*Extended life instruments which are rated for a maximum of 18 lives and are listed in* ***Table 2-2***).

Hence the subject devices i.e., Extended Life instruments were added to the UL Report without performing any testing (*refer to PN 841011-02, Pages 11 and 12 which is provided as* ***Appendix B1*** *in this submission*).

**Table 2-4: Summary of Electrical Safety Test Results per IEC 60601-1** (***refer to the Test Report PN 841011-02 provided as Appendix B1, Page 179***)

| IEC 60601-1 | | | |
|---|---|---|---|
| **11.6.1, TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances** | | | |
| **Clause/ Test Name** | **Test Condition** | **Part Under Test** | **Test Results** |
| 11.6.7 Sterilization | Equipment sterilized by Prevacuum Cycle [redacted] for 4 minutes. Dry time of [redacted] for total of 20 cycles. | Fenestrated Bipolar Forceps<br><br>Large Needle Driver | There was no sign of deterioration. Refer to IEC 60601-2-2 particular within the test report (PN 841011-02 provided as **Appendix B1**) for test results. |

Additionally, testing was performed on a representative instrument (Fenestrated Bipolar Forceps) from the Bipolar instrument family to comply with *IEC 60601-2-2:2017, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, Clause 201.8.8.3.101, "Active Accessory Installation"*. The test results are summarized in **Table 2-5**.

**Table 2-5: Summary of Electrical Safety Test Results per *IEC 60601-2-2, Clause 201.8.8.3.101, "Active Accessory Installation"* (refer to the Test Report PN 841011-02 provided as Appendix B1, Page 240)**

| Clause/ Test Name | Test Condition | Part Under Test | Test Results |
|---|---|---|---|
| IEC 60601-2-2, Clause 201.8.8.3.101, "Active Accessory Installation" | Test samples, other than those marked for SINGLE USE, subjected to cleaning, disinfection and sterilization methods using the number of cycles as outlined in the instructions for use per 7.9.2.12 of Part 1. | Fenestrated Bipolar forceps subjected to 20 cycles of steam sterilization. | There was no sign of deterioration. Refer to IEC 60601-2-2 particular within the test report (PN 841011-02 provided as **Appendix B1**) for test results. |

**Summary of the Electrical Performance testing per the FDA Guidance**

Additional electrical performance testing was performed after subjecting the representative subject devices/instruments (which have *"active components/accessories"*) to multiple reuse and reprocessing cycles (including both manual and automated cleaning process). This testing was performed to ensure that the *"Bipolar Instruments"* within the *da Vinci X/Xi* Extended Lives Instruments family (subject devices as listed in **Table 2-2**) meet the requirements within the *FDA guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, Document Issued on March 9, 2020*. This testing evaluated the electrical performance, specifically the insulation integrity, of the reusable bipolar energy instruments after multiple reuse and reprocessing cycles.

**Representative Instruments used for the Electrical Performance Testing**

Only the IS4000/IS4200 8mm Bipolar instruments within the Extended lives instruments family (as listed in **Table 2-2**) have active electrodes. Per the FDA guidance, this testing is only required for instruments which have *"Active components/Accessories"*. Hence this testing is only applicable to the IS4000/IS4200 8mm Bipolar instruments.

The following instruments were chosen as representative instruments from the IS4000/IS4200 8mm Bipolar instruments for this test based on expected clinical use and design considerations that might impact electrical performance:

- Fenestrated Bipolar Forceps (FBF): The Fenestrated Bipolar Forceps (FBF) shares identical electrical isolation, distal geometry (PEEK) and distal cables with the Long Bipolar Grasper, Maryland Bipolar Forceps and Curved Bipolar Dissector except the metal grip. Similarly, it has the same types of expected surgical tasks as Maryland Bipolar Forceps, Micro Bipolar Forceps and Long Bipolar Grasper. These include dissecting, grasping, manipulating, retracting and coagulating tissue and vessels. However, the number of repetitions of these surgical tasks for FBF are much higher; and expected to be performed at higher loads and/or at more extreme range of motion positions as compared to the other IS4000/IS4200 8mm Bipolar instruments. Thus, the FBF can be considered worse case in terms of expected clinical use.

- Micro Bipolar Forceps: The Micro Bipolar Forceps was included in this test as its construction and materials are unique within the IS4000/IS4200 8mm Bipolar family. It is constructed with an epoxy bonded Ultem yaw cap pulley as opposed to a PEEK overmolded jaw assembly.

- Force Bipolar: The Force Bipolar was included for test as its wrist design is unique within the IS4000/IS4200 8mm Bipolar instrument family. While it shares similar backend, drive-cable architecture, it has a unique distal grip force-amplification architecture, and thus has a unique overmolded grip design, utilizing a different plastic material (PPA) for electrical isolation, and a unique conductor wire routing to accommodate the force-amplification feature.

The test articles were pre-conditioned by exposing the instruments to the applicable number of RC's (Reprocessing Cycles which includes both the manual and automated cleaning methods) and SUC's (Surgical Use Cycles) per the instructions as discussed in the reliability verification protocols as listed in **Table 2-6**.

**Table 2-6: Summary of Instrument Pre-conditioning**

| Instrument | Reprocessing Method | Reliability/Life Test Protocol used for Pre-conditioning | Rated number of human uses | Number of Reprocessing Cycles |
|---|---|---|---|---|
| IS4000/IS4200 Extended Life Fenestrated Bipolar Forceps | Manual | 862223-03P (provided as **Appendix C5** in this submission) | 14 | 19 |
| | Steris W/D | 1086938-01P (provided as **Appendix C6** in this submission) | 14 | 19 |
| IS4000/IS4200 Extended Life Force Bipolar | Manual | 862225-02P (Provided as **Appendix B4** in this submission) | 12 | 17 |
| | Steris W/D | 1088886-01P (provided as **Appendix B5** in this submission) | 12 | 17 |
| IS4000/IS4200 Extended Life Micro Bipolar Forceps | Manual | 1099197-01P (provided as **Appendix B6** in this submission) | 14 | 19 |
| | Steris W/D | | 14 | 19 |

Electrical Performance Test Protocol and Report is listed in **Table 2-7**.

**Table 2-7: Electrical Performance Test Protocol and Report**

| Product Family (Subject Devices) | Master Products | Cleaning Process | Electrical Performance Test Protocol | Electrical Performance Test Report |
|---|---|---|---|---|
| *da Vinci X/Xi* 8mm Extended Life Instruments | Force Bipolar instrument- PN 471405<br><br>Fenestrated Bipolar Forceps - PN 471205<br><br>Micro Bipolar Forceps - PN 471171 | Automated Cleaning process using a compatible Washer-Disinfector (Steris W/D)<br><br>Manual Cleaning process | PN 1002573-05P (*provided as **Appendix B2** in this submission*) | PN 1002573-05R (*provided as **Appendix B3** in this submission*) |

**Rationale for not performing EMC Testing on *da Vinci X/Xi* 8mm Extended Life Instruments**

Per the *FDA guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, Document Issued on March 9, 2020,* according to IEC 60601-2-2, high frequency surgical instruments are intentional emitters of electromagnetic energy and, therefore, emissions testing to IEC 60601-1-2 is only needed for power generators in the idle state (i.e., powered on but surgical energy not activated).

Since emissions testing is performed when the surgical energy is not activated, emissions testing for the *da Vinci X/Xi* 8mm instruments that have been subjected to multiple simulated surgical uses and reprocessing cycles is not applicable and this type of testing is not required to ensure the electrical integrity of the insulation on the instruments.

There are no design differences between the subject and predicate devices, e.g., no new antennae or power cords that could influence the results of EMC testing. Additionally, IEC 60601-1-2 does not require nor specify evaluation to the full number of use lives, and therefore EMC testing for *da Vinci X/Xi* 8mm Extended Life Instruments is not required. The EMC test results for the predicate device still apply to the extended use lives instruments. For FDA reference, we have included EMC test results from the predicate device which are also summarized in **Tables 2-8, 2-9, 2-10 and 2-11**. Refer to EMC Test Report PN 841011-14 which is provided as ***Appendix B7, and its Attachment 1 is provided as Appendix B8*** in this submission.

SUMMARY OF EMC Test RESULTS

**Emissions** were evaluated for the da Vinci (IS4000/IS4200) Surgical System. **Tables 2-8, 2-9 and 2-10** below summarize emissions compliance results (Originally provided in the predicate devices submissions as listed in **Table 2-1**).

**Table 2-8: Radiated Emissions**

| TEST | STANDARD/ SECTION | REQUIREMENT | MEASUREMENT | RESULTS | RESULTS |
|---|---|---|---|---|---|
| PS4000 with new RFID module ACCRX02 and MGPS cable Rev. C<br><br>RE, 30-1000 MHz | CISPR 11, Section 6, Table 4 (Rated input power of ≤ 20 kVA) (Class A, Group 1) | [redacted] | [redacted] | [redacted] | Complied |
| PS4200 with new RFID module ACCRX02<br><br>RE, 30-1000 MHz | | | [redacted] | [redacted] | Complied |

| Table 2-9: Conducted Emissions | | | | | |
|---|---|---|---|---|---|
| **TEST** | **STANDARD/ SECTION** | **REQUIREMENT** | **MEASUREMENT** | **RESULTS** | **RESULTS** |
| PS4000<br>CE, 0.15-30 MHz | CISPR 11,<br>Section 6,<br>Table 2<br>(Rated input power of ≤ 20 kVA)<br>(Class A, Group 1) | [redacted] | [redacted] | [redacted] | Complied |
| PS4200<br>CE, 0.15-30 MHz | | | | | Complied |
| SS4000<br>CE, 0.15-30 MHz | | | | | Complied |
| VS4000<br>CE, 0.15-30 MHz | | | | | Complied |
| PS4000 with new RFID module ACCRX02 with MGPS cable Rev. C<br>CE, 0.15-30 MHz | | | | | Complied |
| PS4200 with new RFID module ACCRX02<br>CE, 0.15-30 MHz | | | | | Complied |

| Table 2-10: Harmonics & Voltage Fluctuations (Flicker) | | | | | |
|---|---|---|---|---|---|
| **TEST** | **STANDARD/ SECTION** | **REQUIREMENT** | **MEASUREMENT** | **RESULTS** | **STATUS** |
| PS4000 Harmonics | IEC 61000-3-2 | Refer to Standard | [redacted] | [redacted] | Complied |
| PS4200 Harmonics | | | | | Complied |
| SS4000 Harmonics | | | | | Complied |
| VS4000 Harmonics | | | | | Complied |
| PS4000 with new RFID module ACCRX02 with MGPS cable Rev. C Harmonics | | | | | Complied |
| PS4200 with new RFID module ACCRX02 Harmonics | | | | | Complied |
| PS4000 Voltage Fluctuations | IEC 61000-3-3 | Refer to Standard | | | Complied |
| PS4200 Voltage Fluctuations | | | | | Complied |
| SS4000 Voltage Fluctuations | | | | - | Complied |

| Table 2-10: Harmonics & Voltage Fluctuations (Flicker) | | | | | |
|---|---|---|---|---|---|
| **TEST** | **STANDARD/ SECTION** | **REQUIREMENT** | **MEASUREMENT** | **RESULTS** | **STATUS** |
| | | | [redacted] | | |
| VS4000 Voltage Fluctuations | | | | - | Complied |
| PS4000 with new RFID module ACCRX02 with MGPS cable Rev. C<br><br>Voltage Fluctuations | | | | - | Complied |
| PS4200 with new RFID module ACCRX02<br><br>Voltage Fluctuations | | | | - | Complied |

**Immunity** for the *da Vinci* IS4000/IS4200 Surgical System was evaluated to the criteria listed in **Table 2-11**.

**Table 2-11: Immunity Testing**

| TEST | STANDARD/ SECTION | REQUIREMENT | CRITERION MET? | RESULTS |
|---|---|---|---|---|
| ESD Enclosure and Patient Ports | IEC 61000-4-2 | [redacted] | Yes | Complied |
| RF EM Field, AM | IEC 61000-4-3 | [redacted] | Yes | Complied |
| RF Proximity Fields | IEC 61000-4-3 | As per standard | Yes | Complied |
| EFT, AC Power Port | IEC 61000-4-4 | [redacted] | Yes | Complied |
| EFT, DC Power Port | IEC 61000-4-4 | N/A; the product does not have a DC power port | | |
| EFT, Signal Ports | IEC 61000-4-4 | [redacted] | Yes | Complied |
| Surge, AC Power Port | IEC 61000-4-5 | [redacted] | Yes | Complied |
| Surge, DC Power Port | IEC 61000-4-5 | N/A; the product does not have a DC power port | | |
| RF, Conducted Disturbances AC Power Port | IEC 61000-4-6 | [redacted] | Yes | Complied |
| | | [redacted] in ISM/Amateur bands | Yes | Complied |
| RF, Conducted Disturbances DC Power Port | IEC 61000-4-6 | N/A; the product does not have a DC power port | | |



 

| Table 2-11: Immunity Testing | | | | |
|---|---|---|---|---|
| **TEST** | **STANDARD/ SECTION** | **REQUIREMENT** | **CRITERION MET?** | **RESULTS** |
| RF, Conducted Disturbances Signal Ports | IEC 61000-4-6 | [redacted] | Yes | Complied |
| | | [redacted] in ISM/Amateur bands | Yes | Complied |
| RF, Conducted Disturbances Patient Ports | IEC 61000-4-6 | N/A; the product does not have any patient port | | |
| Power Frequency Magnetic Field | IEC 61000-4-8 | [redacted] | Yes | Complied |
| Voltage Dips and Interrupts | IEC 61000-4-11 | [redacted] | Yes | Complied |

**User Instruction Documents** were also evaluated in accordance with Clause 5 of IEC 60601-1-2:2014.

- 551457-10 – US Xi I&A User Manual
- 554022-04 – IS4200 System User Manual

Based on the review of the documents listed above, the user instructions provided with the system is compliant with Clause 5 of IEC 60601-1-2:2014.

## EMC DATA ANALYSIS AND RESULTS

The testing records in the EMC Test Report (PN 841011-14 which is provided as ***Appendix B7 and Appendix B8*** in this submission), show that the test articles met the requirements of the standard for every test case. Where the standard references the manufacturer's acceptance criteria for immunity tests, the criteria applied is listed in **Table 2-12**:

**Table 2-12: Criteria applied for EMC Testing**

| Criteria (all systems) | Method for Measuring |
|---|---|
| **System faults** | During testing the system was monitored for faults. If a fault occurs the critical warning icon will be displayed on the touch screen. |
| **Unintentional movement of arms** | While in Ready Mode (in this mode all servo motors in the system are constantly energized and the control system is constantly processing to keep the instruments, camera and master arms in a fixed position) the arms are visually monitored for the duration of the test to confirm that they did not move. This mode is representative of system use and in this state any motion will be readily apparent making this mode the most appropriate for testing. |
| **Loss or frozen image** | Endoscopic view contained a watch (providing continuous motion in the image) that was visually monitored for the duration of the test to ensure that video was not lost or frozen. |
| **Persistent loss of connectivity for Wireless Connectivity Option** | During testing a continuous *ping* was established to monitor connectivity. If communication was interrupted the *ping* would fail. |
| **System and integrated ESU continue to recognize which instruments are connected with no unintended ESU energy delivery** | During Patient-Side Cart immunity testing the instrument tag was written to and read from continuously to ensure that read/write capability was not disrupted. Additionally, one instrument was visually monitored with a near field probe to ensure that no unintentional transmission was triggered by the test. |

During immunity testing, the following conditions are not allowed, in order to meet the basic safety and essential performance criteria:

- Non-recoverable faults that require system power cycling to recover (unless allowed by the medical standard IEC 60601-1)
- Unintentional movement of the arms or instruments
- Loss or frozen image
- Persistent loss of connectivity for the Wireless Connectivity Option
- Loss of instrument recognition by the system or IESU
- Unintentional ESU energy delivery

## FDA Question 3 (Performance Testing)

*You have provided performance testing in Appendices C and D with your submission. With this data, you appear to have set arbitrary performance goals for reliability at confidence of either 85% at 85% or 90% at 90%, depending on the test case. It is unclear why this acceptance criteria is clinically sufficient in evaluating the safety and effectiveness of the extended use devices as compared to the predicate. In addition, you have not provided comparative data to demonstrate how the results are substantially equivalent to the instruments at the predicate use lives. Please provide additional justification and/or comparative reliability data for the instruments at the original use life. This information is needed to understand how your results can be deemed substantially equivalent to the previously cleared instruments.*

**ISI Response**

The appearance of the 85/85 and 90/90 performance goals being arbitrary may be attributed to an insufficient explanation of our risk management process. As explained below, these performance goals are not arbitrary. They apply to different risk scenarios.

Intuitive Surgical, Inc (ISI) approach for establishing performance goals for reliability and confidence for a given test case within the reliability/life testing is based on the clinical and/or usability risk that the device poses to the patient and/or user. The reliability levels are derived from the level of unmitigated risk associated with the failure mode that a particular requirement is mitigating. Per ISI's risk management process, requirements are assumed to impact patient and/or user risk if the requirement originates from a Failure Modes & Effects Analysis (FMEA, pFMEA), Hazard Analysis, Usability Risk Analysis (URA) or Clinical Risk Analysis (CRA). Depending on the pre-mitigated risk-level of a given requirement, the reliability and confidence level for the associated test case is selected based on the applicable *"type code"* which are listed in **Table 3-1**.

**Table 3-1: Required Reliability / Confidence per the applicable Reliability Requirements**

| Type Code | Item/Assembly/Requirement Type<br><br>Table C – Life Test Requirements | Required Reliability / Confidence.<br><br>Minimum Sample Size | Additional Notes |
|---|---|---|---|
| **C1** | Reliability Requirement that meets the following:<br><br>1. FMEA or Hazard Analysis pre-mitigation RPN is less than 64, and<br>2. FMEA or Hazard Analysis pre-mitigation Severity is less than 9, and<br>3. CRA or URA pre-risk index is not equal to I or II.<br>or<br>4. The requirement is not a safety mitigation required by a CRA, URA, FMEA or Hazard Analysis. | 85% / 85%<br><br>4 Samples<br><br>Test duration must demonstrate required reliability based on Weibull analysis | **C1** Type Code is applicable for those requirements that do not originate through ISI's risk management process are, by definition, not risk-based requirements. Verification confirms that non-safety-related features are at least 85% reliable at 85% confidence. |
| **C2** | Reliability Requirement that meets the following:<br><br>1. FMEA or Hazard Analysis pre-mitigation RPN is greater than 63, or<br>2. FMEA or Hazard Analysis pre-mitigation Severity is greater than 8, or<br>3. CRA or URA pre-risk index value is I or II,<br>and<br>4. There is an additional independent mitigation that would limit patient/user risk (i.e. - post-mitigation RPN<64 or post-risk index is III or IV) in the event of a failure to meet the primary requirement, or the pre-mitigation RPN is less than 64 and the pre-mitigation severity is less than 10. | 90% / 90%<br><br>4 Samples<br><br>Test duration must demonstrate required reliability based on Weibull analysis | **C2** and **C3** Type Codes are applicable to safety critical life-test requirements that have additional mitigations to limit patient/user risk must be verified over life by testing a minimum of 4 samples to 90% confidence, 90% reliability (using Weibull analysis). Safety critical life-test requirements that do not have additional mitigations to limit patient/user risk must be verified over life by testing a minimum of 4 samples (8 samples for instruments and accessories) to 95% confidence, 95% reliability (using Weibull analysis). |
| **C3** | Reliability Requirement that meets the following:<br><br>1. FMEA or Hazard Analysis pre-mitigation RPN is greater than 63, or<br>2. FMEA or Hazard Analysis pre-mitigation Severity is greater than 8, or<br>3. CRA or URA pre-risk index value is I or II,<br>and<br>4. There is NO additional mitigation that would limit patient/user risk in the event of a failure to meet the primary requirement. | 95% / 95%<br><br>Systems: 4 Samples.<br><br>I&A: 8 Samples.<br><br>Test duration must demonstrate required reliability based on Weibull analysis | |

The intended use and the applicable clinical/usability risks are the same between the Extended Life *da Vinci X/Xi* 8mm Instruments (subject devices) and the *da Vinci X/Xi* 8mm Instruments rated for 10 lives (predicate devices). The subject and predicate devices are listed in **Table 3-2**.

**Table 3-2: Predicate and Subject Number of lives (uses) and reprocessing cycles for the *da Vinci X/Xi* 8mm Reusable Instruments**

| *da Vinci X/Xi 8mm Reusable Instruments* | Previous Configuration (Predicate Device) | | | Extended Life Configuration (Subject Device) | | |
|---|---|---|---|---|---|---|
| | Model Number | Number of Lives | Number of Reprocessing Cycles | Model Number | Number of Lives | Number of Reprocessing Cycles |
| 8mm Maryland Bipolar Forceps | 470172 | 10 | 15 | 471172 | 14 | 19 |
| 8mm Fenestrated Bipolar Forceps | 470205 | 10 | 15 | 471205 | 14 | 19 |
| 8mm Force Bipolar | 470405 | 10 | 15 | 471405 | 12 | 17 |
| 8mm Large Needle Driver | 470006 | 10 | 15 | 471006 | 15 | 20 |
| 8mm Mega SutureCut Needle Driver | 470309 | 10 | 15 | 471309 | 15 | 20 |
| 8mm Cadiere Forceps | 470049 | 10 | 15 | 471049 | 18 | 23 |
| 8mm ProGrasp Forceps | 470093 | 10 | 15 | 471093 | 18 | 23 |
| 8mm Micro Bipolar Forceps | 470171 | 10 | 15 | 471171 | 14 | 19 |
| 8mm Curved Bipolar Dissector | 470344 | 10 | 15 | 471344 | 14 | 19 |
| 8mm Long Bipolar Grasper | 470400 | 10 | 15 | 471400 | 14 | 19 |
| 8mm Large SutureCut Needle Driver | 470296 | 10 | 15 | 471296 | 15 | 20 |
| 8mm Long Tip Forceps | 470048 | 10 | 15 | 471048 | 18 | 23 |
| 8mm Cobra Graspers | 470190 | 10 | 15 | 471190 | 18 | 23 |

The product risk-levels and the risk mitigations remain the same and there are no differences in terms of the risk mitigations/design requirements between the subject and predicate devices that impact product reliability and performance. Since the performance goals and the required reliability and confidence for a given test case (within the reliability testing) are based on the clinical and/or usability risk that the device poses to the patient and/or user, the criteria used for determining performance and reliability at confidence of either 85% at 85% or 90% at 90% (as appropriate) for the applicable master products remains the same for both the subject and predicate devices. Restated, the performance goals for reliability at confidence of either 85% at 85% or 90% at 90% for the applicable master products (both for the predicate and subject devices) was entirely risk based and uses the same criteria for the *"Type Code"* selection (as listed in **Table 3-1**).

**Tables 3-3 through 3-10** provides a summary of the reliability testing for the Predicate devices i.e., *da Vinci X/Xi* 8mm Instruments (rated for 10 lives as listed in **Table 3-2**) which are reprocessed using the manual cleaning process according to the Reprocessing Instructions which were originally cleared in the 510(k) submissions that are listed in **Tables 3-3 through 3-10.**

The applicable Reliability Test Reports were originally included in the cleared 510(k) submissions as listed in **Tables 3-3 through 3-10**. Subsequently the Reprocessing Instructions for these predicate devices (as listed in **Table 3-2**) were updated and accordingly cleared via K170645. The updates to the Reprocessing Instructions (which were included in K170645) did not impact the reliability of the devices, hence no additional reliability testing was performed, and the Reliability testing for the applicable master products (for the manual cleaning process) summarized in **Tables 3-3 through 3-10** validates the Reprocessing Instructions cleared via K170645.

**Table 3-3: Summary of the Reliability Testing for IS4000/IS4200 8mm Maryland Bipolar Forceps (MBF)**

**Sample Size**: 4 Maryland Bipolar Forceps (MBF) Instruments

**Test Methodology**: The actual production number of human uses was determined by the value of the maximum number of completed life cycles that resulted from execution of the protocol. A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of five (5) was completed to determine the number of human uses.

One life cycle consists of cleaning, sterilizing, taking performance measurements, and performing one simulated surgical use on an instrument.

The instruments were cleaned (using the manual cleaning process) and sterilized according to the Reprocessing Instructions prior to performance measurements and simulated surgical use.

Post cleaning and sterilization, critical parameter performance measurements were taken. They included: friction, grip open angle, pitch and yaw range of motion, bumper position, and intuitive motion. An additional instrument-specific cut test was also performed for instruments with cutting capability. These were chosen based on their criticality to performing a surgical operation. Grip open angle and range of motion are critical to reach the necessary target tissues. An accurate bumper position and maximum cutting force are necessary for precise tissue manipulation. Greater friction in an instrument result in greater hysteresis. Maintaining friction within an acceptable limit, as well as monitoring for intuitive motion, verifies that the test article is appropriately functioning.

After the performance measurements were taken, a surgical simulated use is performed. The simulated surgical use represents actual maneuvers performed during minimally invasive surgical operations. The tasks described above are repeated until the applicable life cycles are achieved, or the instrument fails.

| Predicate Device and applicable 510(k) submissions | Performance Requirements/Acceptance Criteria | Result (Pass/Fail) | Conclusion |
|---|---|---|---|
| Maryland Bipolar Forceps (Cleared via K131861)<br><br>Note: Testing performed on the MBF applies to the following predicate devices:<br><br>o *Fenestrated Bipolar Forceps, Micro Bipolar forceps and Curved Bipolar Dissector which were cleared via K131861.*<br><br>All of the instruments within the Bipolar instrument group (cleared via K131861) utilize the same distal components with the exception of their jaws. All of the bipolar instruments have the same torque limits, except the Micro Bipolar Forceps, which has a lower torque limit. The Maryland Bipolar Forceps has the most rigorous clinical life cycle in this group in terms of amount of distal motion and forces exerted. | o No Service or Repair<br>o Maintain Critical Performance Parameters<br>o Performance Measurements<br>o Distal Cable Inspection<br>o Engagement Recognized by System/Engagement Failures<br>o Inadvertent Detachment<br>o Intuitive Motion<br>o Broken Parts or Pieces<br>o Maintain Cautery Connection<br>o Damaged Electrical Contacts<br><br>A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of 5 was completed, resulting in 10 Human Uses. | PASS | All test articles completed 13 life cycles. Since the performance of the instruments was subsequently determined to be acceptable throughout Life Testing and achieved 13 life cycles, the resulting Number of Human Uses is 10 for Maryland Bipolar Forceps, Fenestrated Bipolar Forceps, Micro Bipolar forceps and Curved Bipolar Dissector. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-4: Summary of the Reliability Testing for IS4000/IS4200 8mm Force Bipolar (FB)**

**Sample Size:** For each test case, 12 samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.

**Test Methodology**: Force Bipolar Instrument was subjected to a series of Reprocessing Cycles (RCs) and Surgical Use Cycle (SUCs) to simulate 10 human uses and 15 reprocessing cycles. Worst case reprocessing cycles (with respect to the manual cleaning process) were utilized during the course of this testing. A Surgical Use Cycle (SUC) consists of performance measurements (range of motion and friction) and simulated surgical use (simulation of the wear that would occur during a single minimally invasive surgical procedure).

| Predicate Device and applicable 510(k) submission | Test Category | Test Requirements/Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|
| | Damage Requirements | Instrument cables do not derail from pulleys.<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Instrument cables do not partially or completely break<br><br>Testing verifies minimum 90% reliability with 90% confidence | | |

| | | | | |
|---|---|---|---|---|
| 8mm Force Bipolar Instrument (Cleared via K180351) | | Instrument does not fail in a way that leaves jaws grasping tissue<br><br>Testing verifies minimum 85% reliability with 85% confidence | PASS | Mercury Bipolar Grasper (Force Bipolar Instrument) met all its requirements throughout its intended life of 10 uses. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| | | Parts or pieces do not detach from instrument that could fall into patient<br><br>Testing verifies minimum 90% reliability with 90% confidence | | |
| | Performance requirements | Verify [redacted] pitch ROM [redacted]<br><br>Testing verifies minimum 85% reliability with 85% confidence | PASS | |
| | | Verify [redacted] grip ROM [redacted]<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Verify [redacted] yaw ROM [redacted]<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Instrument friction remains less than:<br>Roll friction: [redacted]<br>Pitch friction: [redacted]<br>Yaw friction: [redacted]<br>Grip friction: [redacted]<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Instrument is recognized by the system when installed<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Instrument can be engaged successfully by system when installed<br><br>Testing verifies minimum 90% reliability with 90% confidence | | |
| | | Instrument does not inadvertently detach from system during use<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Instrument maintains cautery function during use<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Instrument maintains continuous connection to the electrosurgical generator during use<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |
| | | Instrument retains intuitive motion performance during use<br><br>Testing verifies minimum 90% reliability with 90% confidence | | |
| | | Instrument does not require service or repair<br><br>Testing verifies minimum 85% reliability with 85% confidence | | |

**Table 3-5: Summary of the Reliability Testing for IS4000/IS4200 8mm Long Bipolar Grasper**

The life testing covers features of the IS4000 Long Bipolar Grasper that could be affected by wear on the instrument during use. Based on the justification of using representative instruments for reliability testing, the testing performed on the IS4000 Fenestrated Bipolar Forceps instrument verifies the IS4000 Long Bipolar Grasper's reliability requirements. This testing on the Fenestrated Bipolar Forceps ensures that each requirement listed in **Table 3-5** is met for the Long Bipolar Grasper throughout the rated instrument life of 10 human uses and 15 reprocessing cycles. For each test case, 10 samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.

| Predicate Device and applicable 510(k) submission | Test Category | Test Requirements/Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|
| 8mm Long Bipolar Grasper (Cleared via K150837)<br><br>*Note: The testing performed on the IS4000 Fenestrated Bipolar Forceps instrument verifies the IS4000 Long Bipolar Grasper's reliability requirements.* | Damage Requirements | Instrument drive cables do not derail from pulleys.<br><br>10 units tested to 85% reliability with 85% confidence | PASS | 8mm Long Bipolar Grasper met all its requirements throughout its intended life of 10 uses. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| | | Instrument drive cables do not break<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | | Instrument does not fail in a way that leaves jaws grasping tissue<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | | Instrument does not require service or repair<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Parts or pieces do not detach from instrument that could fall into patient<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | Performance requirements | Instrument friction remains less than:<br>- Roll friction: [redacted]<br>- Pitch friction: [redacted]<br>- Yaw friction: [redacted]<br>- Grip friction: [redacted]<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument range of motion remains at least:<br>- Pitch axis: [redacted]<br>- Yaw axis: [redacted]<br>- Grip open angle: [redacted]<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument is recognized by the system when installed<br><br>10 units tested to 85% reliability with 85% confidence | PASS | |
| | | Instrument can be engaged successfully by system when installed<br><br>10 units tested to 85% reliability with 85% confidence | | |



 

| | | | | |
|---|---|---|---|---|
| | | Instrument does not inadvertently detach from system during use<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument retains intuitive motion performance during use<br><br>10 units tested to 90% reliability with 90% confidence | | |

**Table 3-6: Summary of the Reliability Testing for IS4000/IS4200 8mm Large Needle Driver (LND)**

**Sample Size**: 4 Large Needle Driver (LND) Instruments

**Test Methodology**: The actual production number of human uses was determined by the value of the maximum number of completed life cycles that resulted from execution of the protocol. A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of five (5) was completed to determine the number of human uses.

One life cycle consists of cleaning, sterilizing, taking performance measurements, and performing one simulated surgical use on an instrument.

The instruments were cleaned (using the manual cleaning process) and sterilized according to the Reprocessing Instructions prior to performance measurements and simulated surgical use.

Post cleaning and sterilization, critical parameter performance measurements were taken. They included: friction, grip open angle, pitch and yaw range of motion, bumper position, and intuitive motion. An additional instrument specific cut test was also performed for instruments with cutting capability. These were chosen based on their criticality to performing a surgical operation. Grip open angle and range of motion are critical to reach the necessary target tissues. An accurate bumper position and maximum cutting force are necessary for precise tissue manipulation. Greater friction in an instrument result in greater hysteresis. Maintaining friction within an acceptable limit, as well as monitoring for intuitive motion, verifies that the test article is appropriately functioning.

After the performance measurements were taken, a surgical simulated use is performed. The simulated surgical use represents actual maneuvers performed during minimally invasive surgical operations. The tasks described above are repeated until the applicable life cycles are achieved, or the instrument fails.

| Predicate Device and applicable 510(k) submissions | Performance Requirements/Acceptance Criteria | Result (Pass/Fail) | Conclusion |
|---|---|---|---|
| 8mm Large Needle Driver (Cleared via K131861) | o No Service or Repair<br>o Maintain Critical Performance Parameters<br>o Performance Measurements<br>o Distal Cable Inspection<br>o Engagement Recognized by System/Engagement Failures<br>o Inadvertent Detachment<br>o Intuitive Motion<br>o Broken Parts or Pieces<br><br>A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of 5 was completed, resulting in 10 Human Uses. | PASS | All test articles completed 15 life cycles. Since the performance of the instruments was subsequently determined to be acceptable throughout Life Testing and achieved 15 life cycles, the resulting Number of Human Uses is 10. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-7: Summary of the Reliability Testing for IS4000/IS4200 8mm Mega SutureCut Needle Driver (MSCND)**

**Sample Size**: 4 Mega SutureCut Needle Driver (MSCND) Instruments

**Test Methodology**: The actual production number of human uses was determined by the value of the maximum number of completed life cycles that resulted from execution of the protocol. A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of five (5) was completed to determine the number of human uses.

One life cycle consists of cleaning, sterilizing, taking performance measurements, and performing one simulated surgical use on an instrument.

The instruments were cleaned (using the manual cleaning process) and sterilized according to the Reprocessing Instructions prior to performance measurements and simulated surgical use.

Post cleaning and sterilization, critical parameter performance measurements were taken. They included: friction, grip open angle, pitch and yaw range of motion, bumper position, and intuitive motion. An additional instrument specific cut test was also performed for instruments with cutting capability. These were chosen based on their criticality to performing a surgical operation. Grip open angle and range of motion are critical to reach the necessary target tissues. An accurate bumper position and maximum cutting force are necessary for precise tissue manipulation. Greater friction in an instrument result in greater hysteresis. Maintaining friction within an acceptable limit, as well as monitoring for intuitive motion, verifies that the test article is appropriately functioning.

After the performance measurements were taken, a surgical simulated use is performed. The simulated surgical use represents actual maneuvers performed during minimally invasive surgical operations. The tasks described above are repeated until the applicable life cycles are achieved, or the instrument fails.

| Predicate Device and applicable 510(k) submissions | Performance Requirements/Acceptance Criteria | Result (Pass/Fail) | Conclusion |
|---|---|---|---|
| 8mm Mega SutureCut Needle Driver (Cleared via K131861) | ○ No Service or Repair<br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of 5 was completed, resulting in 10 Human Uses. | PASS | All test articles completed 15 life cycles. Since the performance of the instruments was subsequently determined to be acceptable throughout Life Testing and achieved 15 life cycles, the resulting Number of Human Uses is 10. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-8: Summary of the Reliability Testing for IS4000/IS4200 8mm Cadiere Forceps**

The life testing covers features of the IS4000/IS4200 8mm Cadiere Forceps that could be affected by wear on the instrument during use. Based on the justification of using representative instruments for reliability testing, the testing performed on the IS4000/IS4200 8mm Cadiere Forceps also verifies the IS4000/IS4200 8mm Cobra Grasper's reliability requirements. This testing on the IS4000/IS4200 8mm Cadiere Forceps ensures that each requirement listed in **Table 3-8** is met for the IS4000/IS4200 8mm Cadiere Forceps and the IS4000/IS4200 8mm Cobra Grasper throughout the rated instrument life of 10 human uses and 15 reprocessing cycles. For each test case, 10 samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.

| Predicate Device and applicable 510(k) submission | Test Category | Test Requirements/Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|
| | Damage Requirements | Instrument drive cables do not derail from pulleys.<br><br>10 units tested to 85% reliability with 85% confidence | PASS | |
| | | Instrument drive cables do not break<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | | Instrument does not fail in a way that leaves jaws grasping tissue<br><br>10 units tested to 90% reliability with 90% confidence | | |

| | | | | |
|---|---|---|---|---|
| 8mm Cadiere Forceps (Cleared via K150284)<br><br>*Note: Testing performed on the IS4000/IS4200 8mm Cadiere Forceps also verifies the IS4000/IS4200 8mm Cobra Grasper's reliability requirements.* | | Instrument does not require service or repair<br><br>10 units tested to 85% reliability with 85% confidence | PASS | 8mm Cadiere Forceps and 8mm Cobra Grasper met all its requirements throughout its intended life of 10 uses. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| | | Parts or pieces do not detach from instrument that could fall into patient<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | Performance requirements | Instrument friction remains less than:<br>- Roll friction: [redacted]<br>- Pitch friction: [redacted]<br>- Yaw friction: [redacted]<br>- Grip friction: [redacted]<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument range of motion remains at least:<br>- Pitch axis: [redacted]<br>- Yaw axis: [redacted]<br>- Grip open angle: [redacted]<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument is recognized by the system when installed<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument can be engaged successfully by system when installed<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument does not inadvertently detach from system during use<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument retains intuitive motion performance during use<br><br>10 units tested to 90% reliability with 90% confidence | | |

**Table 3-9: Summary of the Reliability Testing for IS4000/IS4200 8mm Large SutureCut Needle Driver**

The life testing covers features of the IS4000 Large SutureCut Needle Driver that could be affected by wear on the instrument during use. Based on the justification of using representative instruments for reliability testing, the testing performed on the IS4000/IS4200 Mega SutureCut Needle Driver instrument verifies the IS4000/IS4200 Large SutureCut Needle Driver's reliability requirements. This testing on the Mega SutureCut Needle Driver ensures that each requirement listed in **Table 3-9** is met for the Large SutureCut Needle Driver throughout the rated instrument life of 10 human uses and 15 reprocessing cycles. For each test case, 10 samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.

| Predicate Device and applicable 510(k) submission | Test Category | Test Requirements/Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|
| 8mm Large SutureCut Needle Driver (Cleared via K150284)<br><br>*Note: Testing performed on the IS4000 Mega SutureCut Needle Driver instrument verifies the IS4000 Large SutureCut Needle Driver's reliability requirements* | Damage Requirements | Instrument drive cables do not derail from pulleys.<br><br>10 units tested to 85% reliability with 85% confidence | PASS | 8mm Large SutureCut Needle Driver met all its requirements throughout its intended life of 10 uses. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| | | Instrument drive cables do not break<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | | Instrument does not fail in a way that leaves jaws grasping tissue<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | | Instrument does not require service or repair<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Parts or pieces do not detach from instrument that could fall into patient<br><br>10 units tested to 90% reliability with 90% confidence | | |
| | Performance requirements | Instrument friction remains less than:<br>- Roll friction: [redacted]<br>- Pitch friction: [redacted]<br>- Yaw friction: [redacted]<br>- Grip friction: [redacted]<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument range of motion remains at least:<br>- Pitch axis: [redacted]<br>- Yaw axis: [redacted]<br>- Grip open angle: [redacted]<br><br>10 units tested to 85% reliability with 85% confidence | | |

| | | | | |
|---|---|---|---|---|
| | | Instrument is recognized by the system when installed<br><br>10 units tested to 85% reliability with 85% confidence | PASS | |
| | | Instrument can be engaged successfully by system when installed<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument does not inadvertently detach from system during use<br><br>10 units tested to 85% reliability with 85% confidence | | |
| | | Instrument retains intuitive motion performance during use<br><br>10 units tested to 90% reliability with 90% confidence | | |

**Table 3-10: Summary of the Reliability Testing for IS4000/IS4200 8mm ProGrasp Forceps and IS4000/IS4200 8mm Long Tip Forceps**

Note: Two instruments were selected as master products for the Graspers/Retractors family cleared within K131861 which includes the predicate devices (*IS4000/IS4200 8mm ProGrasp Forceps and IS4000/IS4200 8mm Long Tip Forceps rated for 10 lives*).

- The ***ProGrasp Forceps*** exert an amount of force that is mid-level for the Graspers/Retractors group but were selected for testing due to their relatively rigorous clinical life cycle, which involves a relatively large amount of distal motion.
- The ***Tenaculum Forceps*** has the highest level of cable tension in the Graspers/Retractors group and was also selected as a most stringent instrument for testing.

Hence, Reliability/Life Testing performed on the IS4000/IS4200 8mm ProGrasp Forceps and IS4000/IS4200 8mm Tenaculum Forceps covers the life testing for both the ***IS4000/IS4200 8mm ProGrasp Forceps and IS4000/IS4200 8mm Long Tip Forceps (predicate devices rated for 10 lives).***

**Sample Size**: 4 ProGrasp Forceps and Tenaculum Forceps.

**Test Methodology**: The actual production number of human uses was determined by the value of the maximum number of completed life cycles that resulted from execution of the protocol. A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of five (5) was completed to determine the number of human uses.

One life cycle consists of cleaning, sterilizing, taking performance measurements, and performing one simulated surgical use on an instrument.

The instruments were cleaned (using the manual cleaning process) and sterilized according to the Reprocessing Instructions prior to performance measurements and simulated surgical use.

Post cleaning and sterilization, critical parameter performance measurements were taken. They included: friction, grip open angle, pitch and yaw range of motion, bumper position, and intuitive motion. An additional instrument specific cut test was also performed for instruments with cutting capability. These were chosen based on their criticality to performing a surgical operation. Grip open angle and range of motion are critical to reach the necessary target tissues. An accurate bumper position and maximum cutting force are necessary for precise tissue manipulation. Greater friction in an instrument result in greater hysteresis. Maintaining friction within an acceptable limit, as well as monitoring for intuitive motion, verifies that the test article is appropriately functioning.

After the performance measurements were taken, a surgical simulated use was performed. The simulated surgical use represents actual maneuvers performed during minimally invasive surgical operations. The tasks described above were repeated until the applicable life cycles were achieved, or the instrument fails.

| Predicate Device and applicable 510(k) submissions | Performance Requirements/Acceptance Criteria | Result (Pass/Fail) | Conclusion |
|---|---|---|---|
| ProGrasp Forceps and Tenaculum Forceps (Cleared via K131861)<br><br>*Note: Testing performed on the ProGrasp Forceps and Tenaculum Forceps applies to the Long Tip Forceps.* | ○ No Service or Repair<br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>A Weibull Design of Reliability analysis with a 90/90 (reliability and confidence) and a beta of 5 was completed, resulting in 10 Human Uses. | PASS | **Prograsp Forceps**: All test articles completed 13 life cycles. Since the performance of the instruments was subsequently determined to be acceptable throughout Life Testing and achieved 13 life cycles, the resulting Number of Human Uses is 10 for IS4000/IS4200 8mm ProGrasp Forceps. No issues of safety, effectiveness and/or no new risks were identified during the subject test.<br><br>**Tenaculum Forceps**: All test articles completed 15 life cycles, resulting in validation of a Human Use count of 10. No issues of safety, effectiveness and/or no new risks were identified during the subject test.<br><br>Reliability/Life Testing performed on the IS4000/IS4200 8mm ProGrasp Forceps and IS4000/IS4200 8mm Tenaculum Forceps covers the life testing for both the IS4000/IS4200 8mm ProGrasp Forceps and IS4000/IS4200 8mm Long Tip Forceps (predicate devices rated for 10 lives). No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-11** provides a summary of the reliability testing for the Predicate devices i.e., *da Vinci X/Xi* 8mm Instruments (rated for 10 lives as listed in **Table 3-2**) which are reprocessed using the automated cleaning process (using a Steris Washer-Disinfector) according to the Reprocessing Instructions which were cleared in K203632. Master products selected for this testing are listed in **Table 3-11**. The applicable Reliability Test Reports were originally included in K203632.

**Table 3-11: Summary of the Reliability/Life testing performed on *da Vinci X/Xi* 8mm Instruments (rated for 10 lives) to demonstrate compatibility with Steris Washer-Disinfector (Automated Cleaning process)**

| Predicate Device and applicable 510(k) submissions | Performance Requirements/Acceptance Criteria | Result (Pass/Fail) | Conclusion |
|---|---|---|---|
| *da Vinci X/Xi* 8mm Instruments (rated for 10 lives): Cleared via K203632<br><br>*Master products used for testing:*<br>○ *IS4000 Mega SutureCut Needle Driver (MSCND) (PN 470309)*<br>○ *IS4000 Monopolar Curved Scissors (MCS) (PN 470179)*<br>○ *IS4000 Cadiere Forceps (PN 470049)* | ○ No Service or Repair<br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br>○ Maintain Cautery Connection<br>○ Damaged Electrical Contacts<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria**<br><br>All instruments shall pass all test cases with no failures that can be related to the Washer-Disinfector process only. Any instrument failures due to manufacturing, design or handling will not constitute a failure for the purposes of this protocol. Those instruments may be censored and replaced by new instruments of the same type. They will need to start at Life 0 and proceed with the full cycles of testing. | PASS | All test articles completed 10 life cycles which demonstrates compatibility of the *da Vinci X/Xi* 8mm Instruments with the Steris Washer-Disinfector. The instruments passed all test cases with no failures that can be related to the Washer-Disinfector process. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |



 

**Tables 3-12 through 3-14** provides a summary of the reliability testing for the subject devices i.e., *da Vinci X/Xi* Extended Lives 8mm Instruments (as listed in **Table 3-2**) which are reprocessed using the manual cleaning process according to the Reprocessing Instructions which were included in the original submission (K214095). The applicable Reliability Test reports are included in the original submission (K214095). Master products selected for this testing (as applicable) are listed in **Tables 3-12 through 3-14**.

**Table 3-12: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm Extended Lives Bipolar Instruments (manual cleaning process)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm Maryland Bipolar Forceps | 471172 | *Note: Testing was performed on Fenestrated Bipolar Forceps applies to Maryland Bipolar Forceps, Micro Bipolar Forceps, Curved Bipolar Dissector and Long Bipolar Grasper.*<br><br>*Testing summarized in Report PN 862223-03R (Appendix C2 of the original submission, K214095)*<br><br>**Performance Requirements:**<br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br>○ Maintain Cautery Connection<br>○ Damaged Electrical Contacts<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm Maryland Bipolar Forceps, Fenestrated Bipolar Forceps, Micro Bipolar Forceps, Curved Bipolar Dissector and Long Bipolar Grasper Instruments met the reliability requirements throughout fourteen (14) human uses and nineteen (19) reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| 8mm Fenestrated Bipolar Forceps | 471205 | | | |
| 8mm Micro Bipolar Forceps | 471171 | | | |
| 8mm Curved Bipolar Dissector | 471344 | | | |
| 8mm Long Bipolar Grasper | 471400 | | | |

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|---|---|---|---|---|
| 8mm Force Bipolar | 471405 | Testing summarized in Report PN 862225-04R (*Appendix C4 of the original submission, K214095*)<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br>○ Maintain Cautery Connection<br>○ Damaged Electrical Contacts<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm Force Bipolar Instruments met the reliability requirements throughout twelve (12) human uses and seventeen (17) reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-13: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm Extended Lives Needle Driver Instruments (manual cleaning process)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm Large Needle Driver | 471006 | *Testing summarized in Report PN 862211-07R (Appendix C6 of the original submission, K214095)*<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi 8mm Extended Lives* Needle Driver Instruments met the reliability requirements throughout Fifteen (15) human uses and Twenty (20) reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| 8mm Large SutureCut Needle Driver | 471296 | *Testing summarized in Report PN 862212-06R (Appendix C8 of the original submission, K214095)*<br>*Testing performed on the Mega SutureCut Needle Driver applies to Large SutureCut Needle Driver based on the master product justification documented in the test report.*<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | |
| 8mm Mega SutureCut Needle Driver | 471309 | | | |



**Table 3-14: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm Extended Lives Forceps/Graspers Instruments (manual cleaning process)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm ProGrasp Forceps | 471093 | *Testing summarized in Report PN 862214-03R (Appendix C10 of the original submission, K214095)*<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm ProGrasp Forceps met the reliability requirements to support a design life of 18 human uses and 23 reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| 8mm Long Tip Forceps | 471048 | *Testing summarized in Report PN 862221-02R (Appendix C12 of the original submission, K214095)*<br><br>*Note: Testing performed on the Cadiere Forceps applies to the Cobra Grasper and Long Tip forceps per the master product justification documented in the report.*<br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm Cadiere Forceps, Cobra Grasper and Long Tip forceps met the reliability requirements to support a design life of 18 Human uses and 23 reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |
| 8mm Cobra Graspers | 471190 | | | |
| *8mm Cadiere Forceps* | *471049* | | | |

**Tables 3-15 through 3-19** provides a summary of the reliability testing for the subject devices i.e., *da Vinci X/Xi* Extended Lives 8mm Instruments (as listed in **Table 3-2**) which are reprocessed using the automated cleaning process (using a Steris Washer-Disinfector) according to the Reprocessing Instructions. The applicable reliability Test reports are included in the original submission (K214095). Based on the *Master Product Justification PN 1094613, provided in the original submission (K214095) as* ***Appendix D11****,* the following Extended Lives *da Vinci X/Xi* 8mm Instruments were used for reliability testing to demonstrate compatibility of the *da Vinci X/Xi* Extended Lives 8mm Instruments (subject devices as listed in **Table 3-2**) with the automated cleaning process (using a Steris Washer-Disinfector):

- 8mm Large Needle Driver (PN 471006)
- 8mm Fenestrated Bipolar Forceps (PN 471205)
- 8mm Force Bipolar (PN 471405)
- 8mm ProGrasp Forceps (PN 471093)
- 8mm Cadiere Forceps (PN 471049)

**Table 3-15: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm Large Needle Driver (Automated cleaning process- Steris W/D)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm Large Needle Driver | PN 471006 | *Testing summarized in Report PN 1080767-01R (Appendix D6 of the original submission, K214095)*<br><br>**Performance Requirements:**<br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm Large Needle Driver met the reliability requirements to support a design life of 15 human uses and 20 reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-16: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm Fenestrated Bipolar Forceps (Automated cleaning process- Steris W/D)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm Fenestrated Bipolar Forceps | PN 471205 | *Testing summarized in Report PN 1086938-01R (Appendix D2 of the original submission, K214095)*<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br>○ Maintain Cautery Connection<br>○ Damaged Electrical Contacts<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm Fenestrated Bipolar Forceps met the reliability requirements to support a design life of 14 human uses and 19 reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |



**Table 3-17: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm Force Bipolar (Automated cleaning process- Steris W/D)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm Force Bipolar | PN 471405 | *Testing summarized in Report PN 1088886-01R (Appendix D4 of the original submission, K214095)*<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br>○ Maintain Cautery Connection<br>○ Damaged Electrical Contacts<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm Force Bipolar met the reliability requirements to support a design life of 12 human uses and 17 reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-18: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm ProGrasp Forceps (Automated cleaning process- Steris W/D)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm ProGrasp Forceps | PN 471093 | *Testing summarized in Report PN 1084918-01R (Appendix D8 of the original submission, K214095)*<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm ProGrasp Forceps met the reliability requirements to support a design life of 18 human uses and 23 reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**Table 3-19: Summary of Reliability/Life Testing on *da Vinci X/Xi* 8mm Cadiere Forceps (Automated cleaning process- Steris W/D)**

| ***da Vinci X/Xi* Extended Life 8mm Instruments** | **Model Number** | **Performance Requirements/Acceptance Criteria** | **Result (Pass/Fail)** | **Conclusion** |
|---|---|---|---|---|
| 8mm Cadiere Forceps | PN 471049 | *Testing summarized in Report PN 1084981-01R (Appendix D10 of the original submission, K214095)*<br><br>**Performance Requirements:**<br><br>○ Maintain Critical Performance Parameters<br>○ Performance Measurements<br>○ Distal Cable Inspection<br>○ Engagement Recognized by System/Engagement Failures<br>○ Inadvertent Detachment<br>○ Intuitive Motion<br>○ Broken Parts or Pieces<br><br>For each test case, the test samples were tested to a reliability and confidence level of 85%/85% or 90%/90%, depending on each test case's predetermined risk level.<br><br>**Acceptance Criteria:** All test samples must meet all acceptance criteria listed for every test case. | PASS | *da Vinci X/Xi* 8mm Cadiere Forceps met the reliability requirements to support a design life of 18 human uses and 23 reprocessing cycles. No issues of safety, effectiveness and/or no new risks were identified during the subject test. |

**CONCLUSION:**

There are no significant differences in terms of product risk levels or risk mitigations and the risk-based criteria (*Type Code*) used to set confidence/reliability levels remain the same between subject and predicate devices. The reliability testing summary provided in ***Tables 3-3 through 3-19*** demonstrates that the *da Vinci X/Xi* 8mm Extended Lives Instruments (subject devices) and *da Vinci X/Xi* 8mm Instruments (Predicate device), as listed in **Table 3-2** meet the equivalent performance requirements and acceptance criteria. No issues of safety, effectiveness and/or no new risks were identified during the reliability testing. This reliability testing demonstrated compatibility of the subject and predicate devices with both the manual cleaning process and automated cleaning process (using Steris Washer-Disinfector).

Hence the subject devices are substantially equivalent to the predicate devices (as listed in **Table 3-2**).

## FDA Question 4 (Performance Testing)

*With your performance testing, you evaluate cautery in a binary manner (cautery success vs cautery failed). You have not performed any quantitative thermal effects testing to determine whether the thermal characteristics have changed after extended use of the subject device. Extended use and reprocessing of the subject device may introduce microscopic damage and fractures to the instrument which are not readily apparent in general testing. These changes may potentially impact the thermal operating characteristics of electrosurgical instruments. Accordingly, thermal spread evaluation is necessary to understand the safety and effectiveness profile of these instruments. Please provide additional thermal damage data of representative instruments to evaluate this possibility. For additional information, please refer to Section XI part E, of FDA guidance, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" (https://www.fda.gov/media/87995/download). This information is needed to ensure that the electrosurgical characteristics of the extended use instruments are substantially equivalent to the predicate.*

**ISI Response**

Thermal Effects testing was performed to confirm that thermal effects on tissue are comparable between Extended Life IS4000/IS4200 Bipolar Instruments (Test/Subject device) at their end of life (14 lives) and IS4000/IS4200 Bipolar Instruments (Control/Predicate device) at their end of life (10 lives).

The testing was performed in accordance with the requirements within the *FDA guidance, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", Section XI Part E, Thermal Effects on Tissue (Document Issued on March 9, 2020).*

A compatible representative surgical system (i.e., the IS4000/IS4200 *da Vinci* Surgical System) and compatible electrosurgical generator at representative minimum, mid and maximum power setting was used. The Thermal Effects Testing is summarized in the Test Protocol/Test Report as listed in **Table 4-1.**

**Table 4-1: Thermal Effects Test Protocol and Report**

| Product Family (Subject Devices) | Thermal Effects Test Protocol | Thermal Effects Test Report |
|---|---|---|
| *da Vinci X/Xi* 8mm Extended Life Instruments | PN 1098929-01P (provided as **Appendix C1** in this submission) | PN 1098929-01R (provided as **Appendix C2** in this submission) |

IS4000/IS4200 Fenestrated Bipolar Forceps (FBF) was selected as a worst-case representative device based on anticipated clinical use and testing performed on the FBF applies to all the products i.e., electrosurgical instruments within the *da Vinci X/Xi* 8mm Extended Lives Instruments family as listed in **Table 4-2**.

The rationale for selecting IS4000/IS4200 Fenestrated Bipolar Forceps (FBF) as a worst-case representative device for the testing is provided in **Table 4-3**.

**Table 4-2: Predicate and Subject Number of lives (uses) and reprocessing cycles for the *da Vinci X/Xi* 8mm Reusable Bipolar Instruments**

| *da Vinci X/Xi* 8mm Reusable Instruments | Previous Configuration (Predicate Device) | | | Extended Life Configuration (Subject Device) | | |
|---|---|---|---|---|---|---|
| | Model Number | Number of Lives | Number of Reprocessing Cycles | Model Number | Number of Lives | Number of Reprocessing Cycles |
| 8mm Maryland Bipolar Forceps | 470172 | 10 | 15 | 471172 | 14 | 19 |
| 8mm Fenestrated Bipolar Forceps | 470205 | 10 | 15 | 471205 | 14 | 19 |
| 8mm Force Bipolar | 470405 | 10 | 15 | 471405 | 12 | 17 |
| 8mm Micro Bipolar Forceps | 470171 | 10 | 15 | 471171 | 14 | 19 |
| 8mm Curved Bipolar Dissector | 470344 | 10 | 15 | 471344 | 14 | 19 |
| 8mm Long Bipolar Grasper | 470400 | 10 | 15 | 471400 | 14 | 19 |

**Table 4-3: Rationale for selection of the IS4000/IS4200 Fenestrated Bipolar Forceps (FBF) as the Master product for the Thermal Effects Testing**

| Energy Setting | Bipolar Instrument | Extended Number of Human Uses | Rationale |
|---|---|---|---|
| Low mode-10W<br>Standard mode-50W<br>Macro mode-95W | Fenestrated Bipolar Forceps (FBF) | 14 | The Fenestrated Bipolar Forceps (FBF) has the same type of expected surgical tasks as Maryland Bipolar Forceps, Micro Bipolar Forceps, Long Bipolar Grasper. These include dissecting, grasping, manipulating, retracting, and coagulating tissue and vessels. However, the number of repetitions of these surgical tasks for FBF are much higher; and expected to be performed at higher loads than the other instruments (as listed in **Table 4-2**). FBF and Force Bipolar share the same simulated surgical use. But extended life Force bipolar is only rated for 12 human uses in comparison to FBF, which is rated for 14 human uses. Therefore, extended life FBF has energy activations higher than other bipolar instruments. FBF is also exposed to 19 autoclave cycles as a part of its reprocessing, similar to or greater than other extended life bipolar instruments. Higher number of energy activations and exposure to higher temperatures may potentially affect the electrode surface, thus having an impact on the thermal effect.<br><br>Hence, FBF is considered worse case in terms of expected clinical use and was chosen as the representative bipolar instrument for this testing. |

**Energy Settings for Thermal Effects Testing**

A representative maximum, middle and minimum bipolar energy setting on a compatible electrosurgical generator (i.e., Medtronic ForceTRIAD) was tested. For this comparative evaluation, Macro Mode at [redacted] Standard Mode at [redacted] and Low Mode at [redacted] from the ForceTRIAD generator was used as representative maximum, middle and minimum settings, respectively, of all available compatible settings. Based on the mode characteristics, these energy settings maximize potential differences in thermal effect and ensures sufficient rigor to detect meaningful differences in resultant thermal effect.

**RATIONALE FOR USING STANDARD MODE AS DEFAULT ENERGY SETTING**

The mid power setting was approximately [redacted] (as noted in **Table 4-4**). The Subject Extended Life IS4000/IS4200 Bipolar instruments (rated for 14 lives) and Predicate IS4000/IS4200 Bipolar instruments (rated for 10 lives) do not have a 'default' energy setting associated with their compatible generators. Therefore, ForceTRIAD's [redacted] was tested as the representative 'default setting'.

**Table 4-4: Energy modes and settings tested**

| Energy Type | ForceTRIAD Energy Settings | |
|---|---|---|
| | Mode | Power (Watts) |
| Bipolar Coag | Low | [redacted] |
| | Standard | |
| | Macro | |

**Instrument Preconditioning**

Test and Control samples were preconditioned by exposing the instruments to multiple simulated surgical uses and reprocessing cycles. The Reprocessing cycles include both manual and automated cleaning methods. Preconditioning for test and control devices was performed according to Reliability/Life Testing Protocols as listed in **Table 4-5** and includes the procedures for exposing the instruments to multiple simulated surgical uses (SSUs) and reprocessing cycles (RCs).

Two groups of instruments were evaluated under this test:

- Instruments that were subjected to manual cleaning process
- Instruments that were subjected to automated cleaning process using a Steris Washer-Disinfector.

**Table 4-5: Summary of Instrument Pre-conditioning**

| Instrument | Reprocessing Method | Reliability/Life Test Protocol used for Pre-conditioning | Rated number of human uses | Number of Reprocessing Cycles |
|---|---|---|---|---|
| Control Device- IS4000/IS4200 Fenestrated Bipolar Forceps | Manual | 862223-02P (provided as **Appendix C3** in this submission) | 10 | 15 |
| | Steris W/D | 1059826-03P (provided as **Appendix C4** in this submission)<br><br>*Note: Attachment 13 of the protocol includes the performance measurements for the IS4000/IS4200 Fenestrated Bipolar Forceps. Hence Attachments 1 through 12 are not included in this protocol.* | 10 | 15 |
| Test Device- IS4000/IS4200 Extended Life Fenestrated Bipolar Forceps | Manual | 862223-03P (provided as **Appendix C5** in this submission) | 14 | 19 |
| | Steris W/D | 1086938-01P (provided as **Appendix C6** in this submission) | 14 | 19 |

**Electrode application on tissue**

In order to have a controlled test method for comparing thermal effect on tissue, the electrode orientation and duration of energy application were consistent between the test and control instrument. Testing was performed on tissue by grasping onto the sample with the entire length (excluding tangs) and width of the intended grasping surface. Consistency of jaw gap (i.e., the space between each bipolar electrode) was ensured for each comparative scenario type by closing the MTMs to the same position (e.g., "bumper") for each activation. Energy was applied continuously for [redacted] The methods of energy application and electrode contact with tissue chosen for this testing are representative of worst-case surgical use and ensure sufficient rigor to detect differences in resultant thermal effect between the test and control instruments.

**Tissue selection and requirements**

Testing was performed on ex vivo porcine skeletal muscle, liver, and kidney tissue types. These tissue types represent a range of densities common for soft tissues according to *International commission on radiological protection, Adult reference computational phantoms, ICRP Publication 110, Ann. ICRP 39 (2), 2009 pp.48-51 Table A.1.*

This study compared thermal effect zones between the test and control article(s) while controlling for consistency of test setup parameters between test/control articles. Tissue samples for all tissue types used in this testing met the following requirements:

- Tissue samples were prepared in a consistent manner for a controlled test (e.g., controlled tissue thickness and tissue size).
- Size of tissue samples were sufficient as to allow for the full development of the thermal damage zone without being influenced by boundary conditions (e.g., tissue too thin, tissue not wide enough).
- Tissue was fresh.
- Tissue was refrigerated until testing.
- Tissue quality was viable for testing.

**Control of Tissue Temperature**

Prior to applying energy to a tissue sample, the tissue was brought to a representative baseline temperature using a water bath heated to [redacted] Samples were enclosed in a plastic bag to prevent direct contact with water in the heated water bath. This temperature was chosen to simulate expected tissue temperatures during surgery. For the duration of energy application, tissue was removed from the heated water bath (to prevent removal of heat/energy from tissue samples by water in the bath). The tissue was positioned in the test setup during energy activation, and then returned to the heated water bath following completion of energy delivery. During energy activation, the tissue sample was grasped between the jaws of the instrument. Testing (i.e., time the tissue sample was out of the heated water bath) for each sample took no more than [redacted] to ensure that tissue temperature did not vary significantly from baseline due to an extended time outside of the water bath.

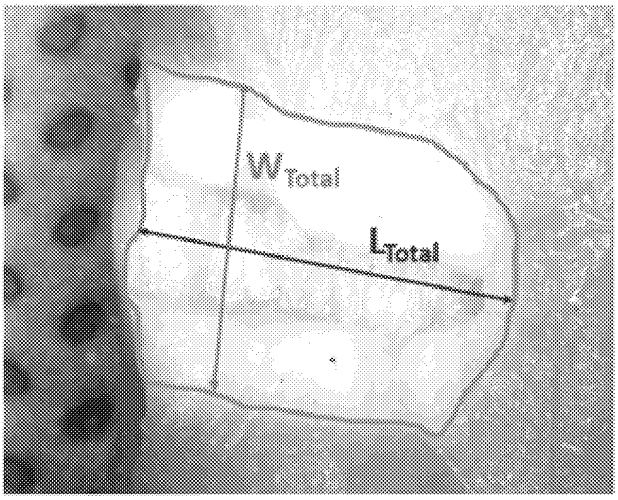
**Thermal Effect Measurement**

The thermal damage zone (i.e., thermally effected zone) is defined as the total region of thermal damage (e.g., abnormal tissue discoloration, charring, blanching) to tissue, including the area where the active electrode contacts tissue. Maximum length and width of thermal damage was directly measured for bipolar energy modes. Depth of bipolar thermal damage on tissue is dependent on tissue sample thickness and was evaluated in this testing. Tissue thickness was

being controlled for and therefore has no effect on comparisons made between bipolar thermal effects.

For bipolar samples, the surface area of thermal effect was directly measured in place of volume. No volume estimation was made because the volume of thermal effect would also require a value for depth, which was not being measured because tissue thickness (i.e., depth) was being controlled for and therefore has no effect on comparisons made between bipolar thermal effects. Image analysis under a light microscope has been shown by an independent histopathologist to be a reliable and accurate alternative to histomorphometry for measuring thermal effect in ex vivo tissue for both monopolar and bipolar RF energy types (refer to *Test Report for Comparing Histology to Macroscopic Imaging for Measuring Thermal Damage on Tissue, PN 1039730-01R,* which is provided as **Appendix C7** in this submission). Therefore, thermal effect measurements were made from images taken with a light microscope. Each sample was be imaged under a microscope and thermal effect measurements were taken from the images using photo measurement tool software. Ex-vivo porcine muscle, kidney and liver raw data were measured and analyzed in the same manner. The measurements were performed by a blinded tester with adequate training to execute this protocol.

Thermal effect was assessed by directly measuring the maximum applicable dimension (length, width) of tissue discoloration on images taken using microscope images as seen in **Figure 4-6** Length and width measurements were made orthogonal to each other.
The *"Measured Images"* for the applicable samples (*Attachment 9 of the Report PN 1098929-01R, provided as* ***Appendix C2*** *in this submission*) are provided as a *Miscellaneous Zip File folder in the E-copy*. These measured images correspond with the Sample numbers which are listed in *PN 1098929-01R, Attachment 2, Raw Data Sheets, provided as* ***Appendix C2*** *in this submission.*




Total length and total width thermal effect measurements for bipolar modes. Additionally, a surface area measurement will be provided for the entire thermally affected area (encircled in blue, above).

**Figure 4-6: Method for measuring Thermal effect for each enery type**

## DATA ANALYSIS AND CONCLUSION

Average Thermal Effects Length, width and area measurements are provided in *PN 1098929-01R, Attachment 3, Data Tables and Graphs* provided as **Appendix C2** in this submission. For ease of review these measurements for all the different tested tissue types are provided in **Figures 4-7, 4-8 and 4-9.**

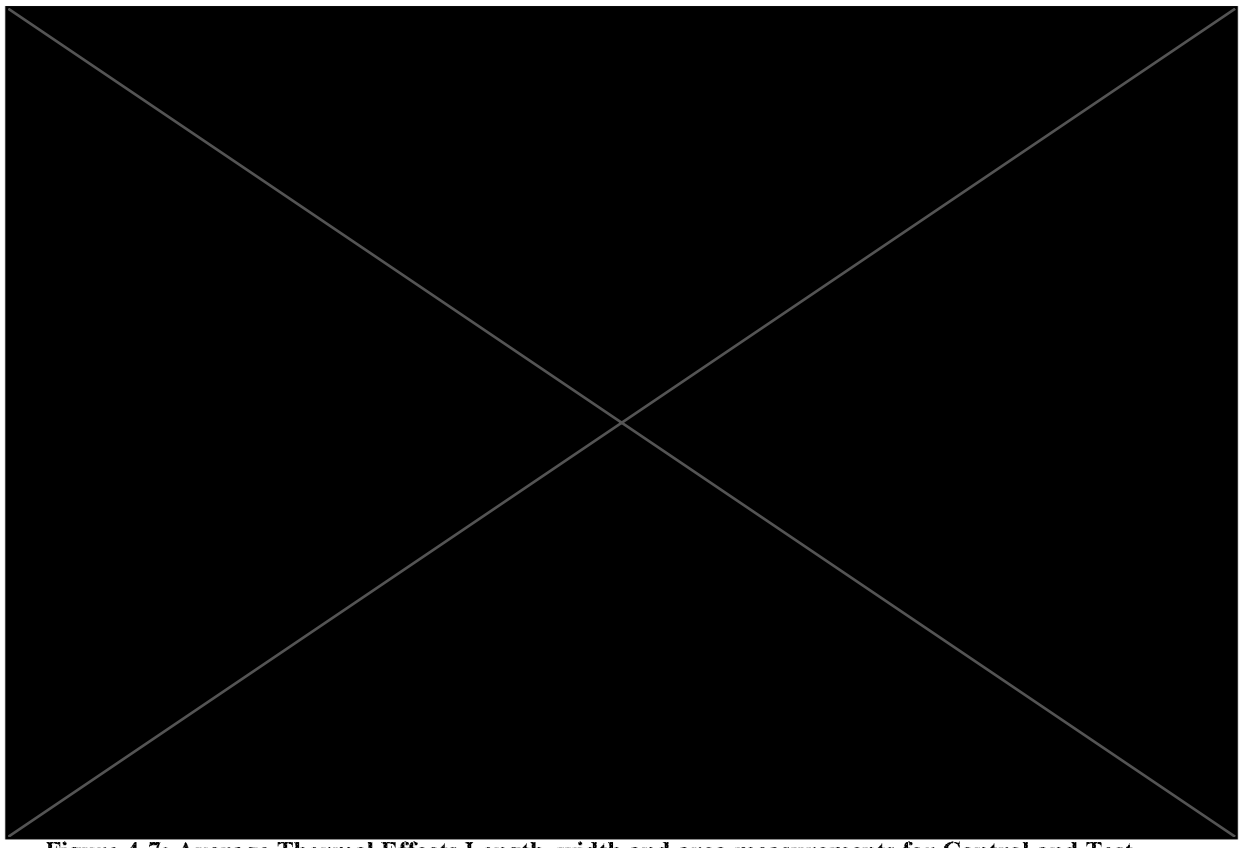


**Figure 4-7: Average Thermal Effects Length, width and area measurements for Control and Test Instruments (FBF), Ex-vivo Porcine Skeletal Muscle**

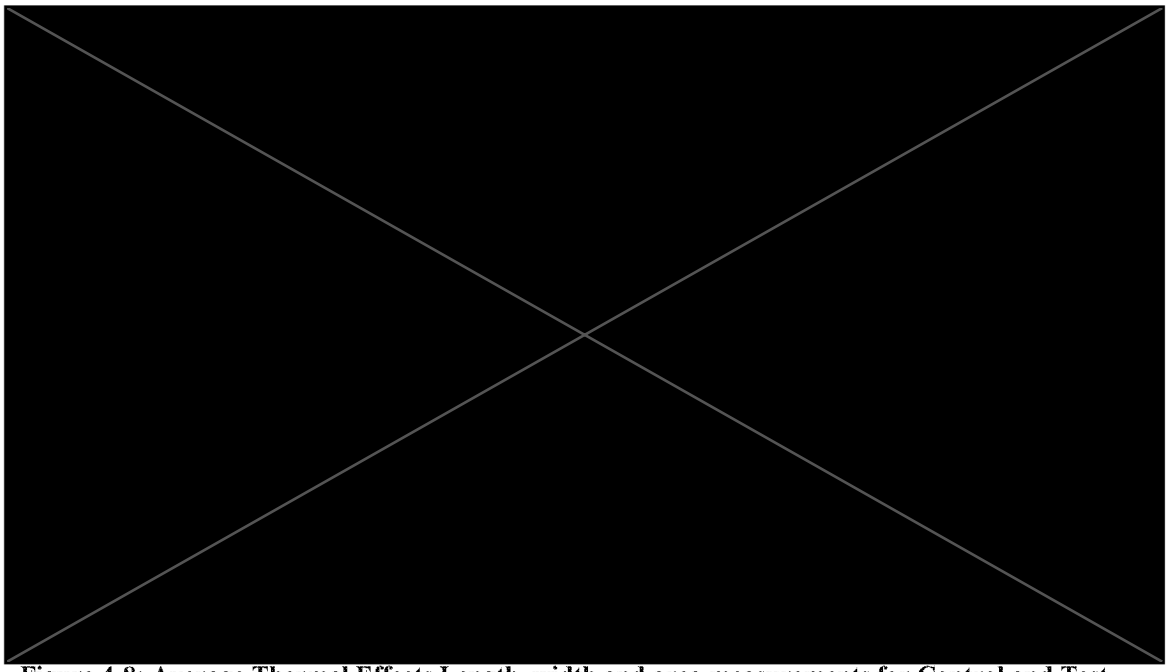


**Figure 4-8: Average Thermal Effects Length, width and area measurements for Control and Test Instruments (FBF), Ex-vivo Porcine Liver**

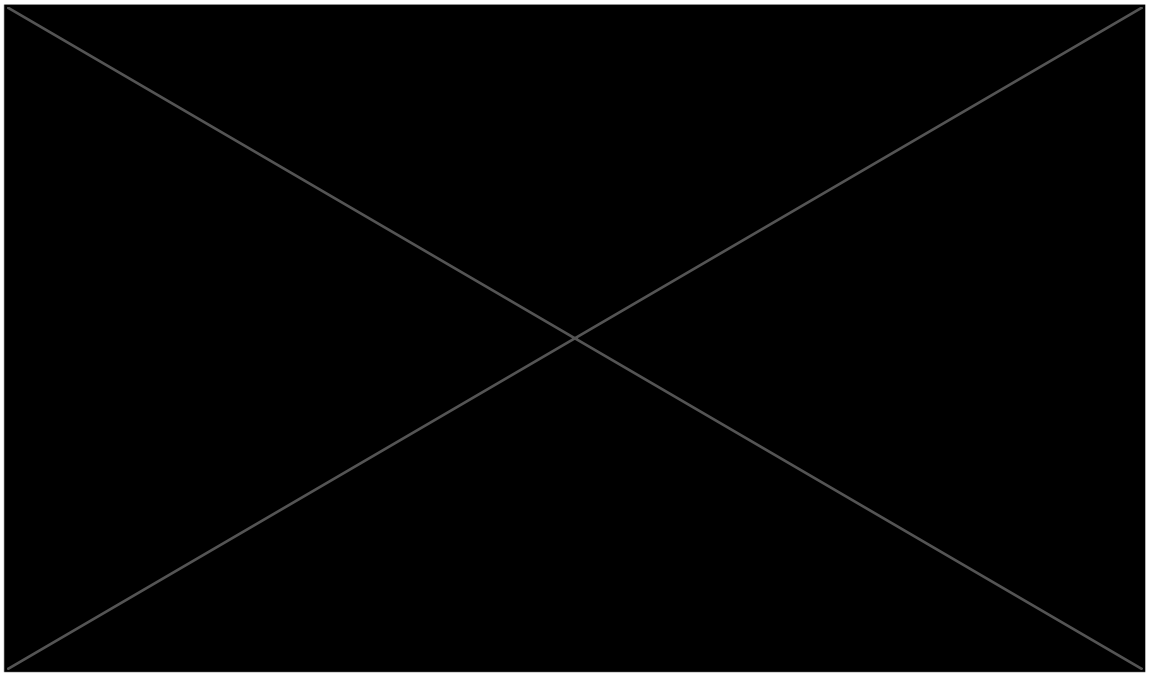


**Figure 4-9: Average Thermal Effects Length, width and area measurements for Control and Test Instruments (FBF), Ex-vivo Porcine Kidney**

Thermal effect measurements were compared statistically using Mann-Whitney Wilcoxon (MWW) Test, with a separate analysis performed for each measurement (e.g length, width and area). A total of 216 observations with 108 records in both the Control FBF and Test FBF were analyzed. The measurements were taken under a combination of tissue type, power setting and reprocessing method with each combination containing 6 samples.

The acceptance criteria for the Test and Control FBF instruments is listed in **Table 4-10**.

**Table 4-10: Acceptance Criteria**

| Acceptance Criteria | Notes |
|---|---|
| Differences in thermal effect that are not shown to be statistically significant are acceptable. | A Mann-Whitney Wilcoxon Test comparison between thermal effect measurements for test and control instrument did not find statistical evidence [redacted]) to suggest there is a difference in thermal effects between the instruments. |
| **OR** | |
| Differences in thermal spread of less than approximately [redacted] lateral distance are acceptable. | The thermal spread measurement technique has an empirical measurement error of approximately [redacted], which is within the expected range of accuracy for thermal spread analysis using ex vivo tissue samples (as reported by an independent pathologist in *Report PN 1039730-01R provided as **Appendix C7** in this submission*). Therefore, differences in thermal spread of less than approximately [redacted] may not be detectable using this image analysis technique. |

Statistical Analysis was performed (*which is summarized in Report PN 1098929-01R, Attachment 4, Statistical Analysis provided as **Appendix C2** in this submission*) to determine if the results from an experimental design indicate a performance difference which is statistically significant between the IS4000/IS4200 Extended Life Bipolar Instruments (Test/Subject device) and the IS4000/IS4200 Bipolar Instruments (Control/Predicate device).

Tissue samples were burnt under various conditions (e.g., tissue type, temperature) and the size of the thermal effects were measured in three different dimensions i.e., Width, Length & Area. It is of key interest to know if statistical evidence exists that the size of the thermal effect differs when comparing the two instruments.

**The following are the key conclusions from this statistical analysis:**

Utilizing the Mann-Whitney Wilcoxon (MWW) Test we have insufficient evidence to identify a difference in medians for Length, Width and Area of thermal effect based on Instrument used. As evidenced in the three separate MWW results (as summarized in **Table 4-11**), where the p-value > [redacted] there is **insufficient evidence** of the response variable median differing based on the Instrument used. This finding holds true for all three metrics of interest. Instruments in the Control and Test group should be expected to have similar thermal effect sizes for Width, Length and Area.

**Table 4-11: Summary of Analysis**

| Mann-Whitney Wilcoxon Test | | |
|---|---|---|
| **Type of Comparison** | **P Value** | **Pass/Fail** |
| Width of Thermal Effect | [redacted] | Pass |
| Length of Thermal Effect | | Pass |
| Surface Area of Thermal Effect | | Pass |

## CONCLUSION

The Extended Life IS4000/IS4200 Bipolar Instruments (Test/Subject device) was found to have acceptable and similar thermal effects when compared with IS4000/IS4200 Bipolar Instruments (Control/Predicate device).